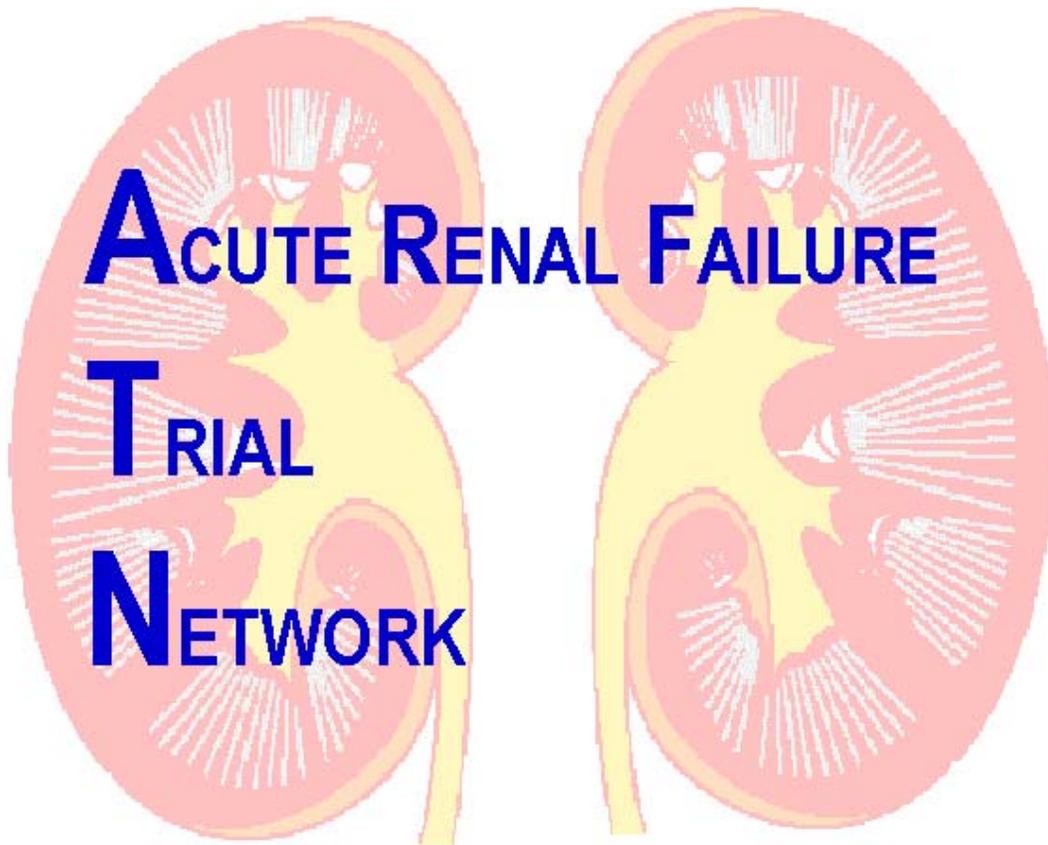


# VA COOPERATIVE STUDY #530:

## *Intensive vs Conventional Renal Support in Acute Renal Failure*



*Department of Veterans Affairs*  
**COOPERATIVE STUDIES PROGRAM**



National Institute of  
Diabetes & Digestive &  
Kidney Diseases

# **OPERATIONS MANUAL**

**Version 4.0 September 15, 2006**



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## **I. INTRODUCTION**

### **A. Purpose of the Operations Manual**

The operations manual is a guide to the day-to-day conduct of VA Cooperative Study #530, the VA/NIH Acute Renal Failure Treatment Network (ATN) Study, and is intended to supplement the study protocol.

This volume outlines general procedures and guidelines for participating investigators and study personnel. It is extremely important that the study be conducted in as uniform a manner as possible at each site. We urge you to read and become familiar with the study protocol and the operations manual. Be sure to consult both the operations manual and study protocol often and to contact either the Chairman's office or the West Haven Coordinating Center if you have any questions or need additional information.

This clinical trial will be carried out in accordance with the guidelines for Good Clinical Practice (GCP). These guidelines include the Guidelines for the Cooperative Studies Program as well as the guidelines for the International Conference on Harmonization (ICH).

### **B. The VA Cooperative Studies Program**

The VA Cooperative Studies Program (CSP), a division of the Department of Veteran's Affairs Office of Research and Development, was established to provide coordination and collaboration for multicenter research studies that fall within the purview of the VA.

Cooperative studies are those in which investigators from two or more medical centers agree to study collectively a selected problem in a uniform manner, using a common protocol with central coordination. There are 18 VA sites and 9 non-VA sites participating in this study.

The investigators and study coordinators for these 27 sites are listed in Section III.B of the Operations Manual.

Although cooperative studies are generally not appropriate for the early development and refinement of new therapeutic techniques, they are particularly advantageous in the later stages of evaluation of safety, efficacy and cost effectiveness of health care interventions that have already had the necessary preliminary trials in humans. Clinical trials and health services research studies of this type, as well as some epidemiological studies, can benefit from a multicenter approach that facilitates the accumulation of patient samples that are:

- Sufficiently large to provide a definitive answer to the research questions. For medical conditions that are relatively rare, cooperative studies may be the only feasible approach. Even in more common conditions, knowledge may be accumulated more rapidly by pooling the observations made in several facilities.
- Sufficiently diverse to permit broad generalization of results.

The CSP currently has five statistical/administrative coordinating centers, one pharmacy coordinating center, one economics coordinating center, and three epidemiological research centers. The five Cooperative Studies Program Coordinating Centers (CSPCCs), located at the VA Medical Centers in Boston, MA, Hines, IL, Palo Alto, CA, Perry Point, MD, and West Haven, CT, provide biostatistical collaboration, data processing and management, and analysis for CSP studies and also ensure their compliance with Cooperative Studies Program guidelines. There is a Human Rights Committee established at each Coordinating Center that reviews the ethical aspects of proposed studies.

The Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC) is affiliated with the VAMC in Albuquerque, NM. The CSPCRPCC was established to provide additional resources for all CSP studies that involve drugs or devices. Personnel from this center help in the planning and development of the study, participate in monitoring the study, serve as liaison between the CSP, the pharmaceutical industry and the Food and Drug Administration (FDA), provide guidance and information on FDA regulations and review and distribute study drugs and devices. Also located in this center is the Site Management and Review Team (SMART), the quality assurance unit of CSP.

The economics coordinating center is the Health Economics Resource Center (HERC), located at the Palo Alto VAMC. HERC staff plan economic analyses for CSP trials, monitor collection of economic data, and perform cost and cost-effectiveness analyses.

In a Cooperative study, certain persons and groups have specific responsibilities. This Operations Manual will identify the individuals involved in the VA/NIH ATN Study and their responsibilities.

## **C. Ethics in Conducting a Cooperative Study**

A VA Cooperative Studies Program (CSP) study is conducted under the VA guidelines for ethical practices and the Good Clinical Practices (GCP). Additional information on GCP is given in Section IV of the Operations Manual.

### **1. Informed Consent**

Each patient or patient surrogate must sign and date an informed consent form to participate in a CSP study. Each patient/surrogate must be allowed to read (or have read to him/her) the informed consent form in order to have some understanding of the study before

discussing it with the investigator. If the original informed consent is signed by a surrogate and the patient regains decision making capacity on or before day 365 post-randomization, written informed consent must be obtained from the patient. The informed consent process is presented in detail in Section VI of the Operations Manual.

Failure to obtain informed consent will result in disciplinary action by the Chief Research and Development Officer and could result in the dismissal of the participating site investigator. The site investigator, or his/her designee, must administer the informed consent form and signatures must be witnessed by a person unrelated to the study. While the site investigator need not be present during the actual informed consent signing, he/she or another appropriate physician/clinician familiar with the study must be available sometime during the informed consent process to answer any medical questions that the potential participants might have. A dated progress note in the patient's medical chart **MUST** be completed indicating that informed consent has been obtained, who has provided consent (i.e., the patient or a surrogate decision-maker if the patient lacks decision-making capacity), and that the patient has entered the study.

At VA sites, the original of the completed and signed informed consent will be filed in the patient's study folder and a copy will be filed in the patient's medical record. At non-VA sites, the original or a copy of the signed informed consent will be filed in the patient's study folder and the patient's medical record, consistent with current policy at the participating site. A copy of the signed informed consent is given to the patient. A copy of the informed consent form will also go the local Research Office at each participating medical center for placement in the IRB file if this is a local requirement.

## **2. Patient Confidentiality**

It is CSP policy to protect the confidentiality of patient study data to the extent permitted by law. Patient identifiers, such as names or social security numbers, will not routinely be placed on study data forms. A unique, study-generated patient identifier number will be assigned to each patient and used for the duration of the study. Patient identifying information will be maintained at the participating center. However, in many studies, such as this one, it may be necessary for the CSPCC to have patient identifying information such as addresses or social security numbers. Examples of such circumstances include the need to obtain data from VA central databases, the need for long-term follow-up of patients by CSPCC, or the need to send letters/surveys to patients from the CSPCC or from a participating medical center. When such information is required by the CSPCC, it must be provided on a separate form or recorded on VA form 10-1086 (Informed Consent), which is submitted to the CSPCC. At the CSPCC, patient identifier information, both paper and electronic versions, will be kept in separate files away from the main data files.

## **3. Yearly Medical Center Reviews**

According to VA policy, every study involving human subjects must be reviewed at least annually by the participating medical center's R&D Committee and Human Subjects Subcommittee/Institutional Review Board. Similar rules also apply to studies performed at non-federal institutions receiving federal funds. It is the responsibility of the site investigator and the R&D Committee and the Human Subjects Subcommittee/Institutional Review Board to ensure that these yearly reviews occur.

The CSPCC will notify the site investigators and the ACOS for R&D of an impending review two or three months in advance. The CSPCC will also collect and maintain copies of appropriate committee minutes and of yearly reviews. If it is not the policy of a committee to release the minutes, a letter from the committee chairperson stating the date that the annual review took place will be acceptable. If yearly reviews are not done in a timely fashion, the participating center will be put on probation.

## **II. OVERVIEW OF STUDY DESIGN**

### **A. Executive Summary**

Acute renal failure (ARF) is the abrupt loss of kidney function resulting in the failure to excrete urea and other nitrogenous waste products. The incidence of ARF in hospitalized patients varies between 1% and 15%, depending upon the population at risk and the criteria used for defining renal failure. Based on a review of ICD-9 codes of discharge diagnoses from the Austin Automation Center Patient Treatment File for Fiscal Year 1999, the incidence of ARF within the VA is approximately 3.1%. There is no effective pharmacologic therapy for the treatment of ARF; management is primarily supportive, with renal replacement therapy serving as the cornerstone in patients with severe ARF. The mortality rates associated with ARF have remained very high despite advances in the use of hemodialysis and other renal replacement therapies over the past 50 years. Mortality rates from recent series continue to exceed 50%. Many fundamental issues in the management of renal replacement therapy in ARF remain to be resolved including the indications for and timing of initiation of therapy, the optimal dose and modality of therapy, the selection of dialysis membranes, the composition of dialysate and replacement fluids, and indications for the discontinuation of therapy. Several recent clinical studies have suggested that more intensive renal support may result in improved survival. These studies, however, have had significant limitations and have not been widely accepted in clinical practice. This study will compare a strategy of intensive renal support to conventional management of renal replacement therapy in critically ill patients with acute renal failure.

Our primary hypothesis is that intensive renal support decreases mortality in critically ill patients with acute renal failure as compared to conventional management of renal replacement therapy. Secondary hypotheses are that intensive renal support in critically ill patients with acute

renal failure will shorten the duration of ARF and decrease the incidence and duration of non-renal complications as compared to conventional management.

This study is a multi-center, prospective, randomized, parallel-group trial of two strategies for the management of renal support in acute renal failure in critically ill patients. For the purpose of this study, acute renal failure will be defined as an increase in serum creatinine of  $\geq 2$  mg/dL ( $\geq 1.5$  mg/dL in women) over a period of  $\leq 4$  days or acute oliguria (urine output  $< 20$  mL/hour) for  $> 24$  hours. Patients will be enrolled if they have ARF clinically consistent with a diagnosis of acute tubular necrosis and if the primary treatment team is planning on initiating renal support. Patients with chronic kidney disease, defined as a pre-morbid serum creatinine  $> 2.0$  mg/dL (1.5 mg/dL in women), and patients with acute renal failure not due to ATN based on clinical criteria will be excluded. In addition, in order to exclude patients with relatively mild disease, in whom ATN is not associated with high mortality, patients will be included only if they have evidence of at least one non-renal organ failure or the presence of sepsis.

Patients will be randomized in a 1:1 ratio to be treated using either a strategy of intensive renal support or conventionally recommended management of renal replacement therapy for their ARF. In both arms of the study, dialysis will be initiated using the same criteria. In the intensive therapy arm, renal support will be provided as intermittent hemodialysis on a 6-times per week basis (target delivered spKt/V of 1.2-1.4/treatment), as compared to a 3-times per week basis (target delivered spKt/V of 1.2-1.4/treatment) in the conventional therapy arm. In both arms, for hemodynamically unstable patients (cardiovascular SOFA score: 3-4), renal support will be provided as continuous venovenous hemodiafiltration (dosed at 35 mL/kg/hr in the intensive dose arm and 20 mL/kg/hr in the conventional dose arm) or as sustained, low-efficiency dialysis (SLED) provided 6-times per week in the intensive therapy arm and 3-times

per week in the conventional therapy arm. Protocol therapy will be continued until renal function recovers or until day 28. Patients who remain dialysis dependent when ready for discharge from acute care, or after day 28, whichever comes first, will be taken off of protocol treatment and will be prescribed further dialysis at the discretion of their treating physician.

The primary study end-point will be 60-day all-cause mortality. Secondary end-points will include all-cause hospital mortality, 1-year all-cause mortality, and recovery of renal function. Duration of renal support, ICU and hospital length of stay, discharge to “home” not requiring dialysis, and the development and/or recovery of non-renal organ failure (assessed by SOFA organ system scores) during renal support will also be assessed. An economic analysis of the treatment strategies will also be performed.

We postulate that the intensive treatment strategy will result in a 10% reduction in mortality from 55% to 45%. Using a 2-sided test of significance with  $\alpha= 0.05$ , a sample size of 1164 will be required to test the primary hypothesis with 90% power, assuming a 10% drop-out rate.

This study is jointly funded by the VA Cooperative Studies Program and the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH). Eighteen VA sites and nine non-VA sites are participating in order to accrue a total of 1164 patients. Each VA site will be expected to enroll approximately 27 patients (9 patients per year), and each non VA-site will be expected to enroll 84 patients (28 per year), during 3 years of intake. Each patient will be followed for a maximum of 60 days, for an overall study duration of 38 months. Secondary follow-up of each patient will occur at 12 months.

## Overview of Study Design

### Study Population

#### *Inclusion Criteria*

- Acute renal failure clinically consistent with a diagnosis of ATN defined as
  - clinical setting of acute ischemic or nephrotoxic injury
  - and
  - oliguria (average urine output < 20 mL/hr) for > 24 hours; or an increase in serum creatinine of  $\geq 2.0$  mg/dL ( $\geq 1.5$  mg/dL in females) over a period of  $\leq 4$  days
- Plan for renal replacement therapy by clinical team
- Receiving care in a critical care unit
- One non-renal organ failure (SOFA organ system score  $\geq 2$ ) or sepsis
- Age  $\geq 18$  years
- Patient/surrogate willing to provide informed consent

#### *Exclusion Criteria*

- Premorbid serum creatinine > 2 mg/dL (> 1.5 mg/dL in females)
- Acute renal failure clinically believed to be due to an etiology other than ATN
- More than 72 hours since meeting both of the following:
  - fulfillment of definition of ARF
  - BUN > 100 mg/dL
- > 1 hemodialysis treatment or > 24 hours of CRRT
- Prior kidney transplant
- Pregnancy
- Prisoner
- Weight > 128.5 kg
- Non-candidacy for renal replacement therapy
- Moribund state
- Patient not expected to survive 28-days because of an irreversible chronic medical condition
- Comfort-measures only status
- Participation in a concurrent interventional study
- Patient/surrogate refusal
- Physician refusal

### Randomization

- 1:1 randomization to treatment arms
- Stratification of randomization by:
  - site
  - oliguria
  - SOFA cardiovascular score (0-2 vs 3-4)

### Sample Size

- 582 patients per group

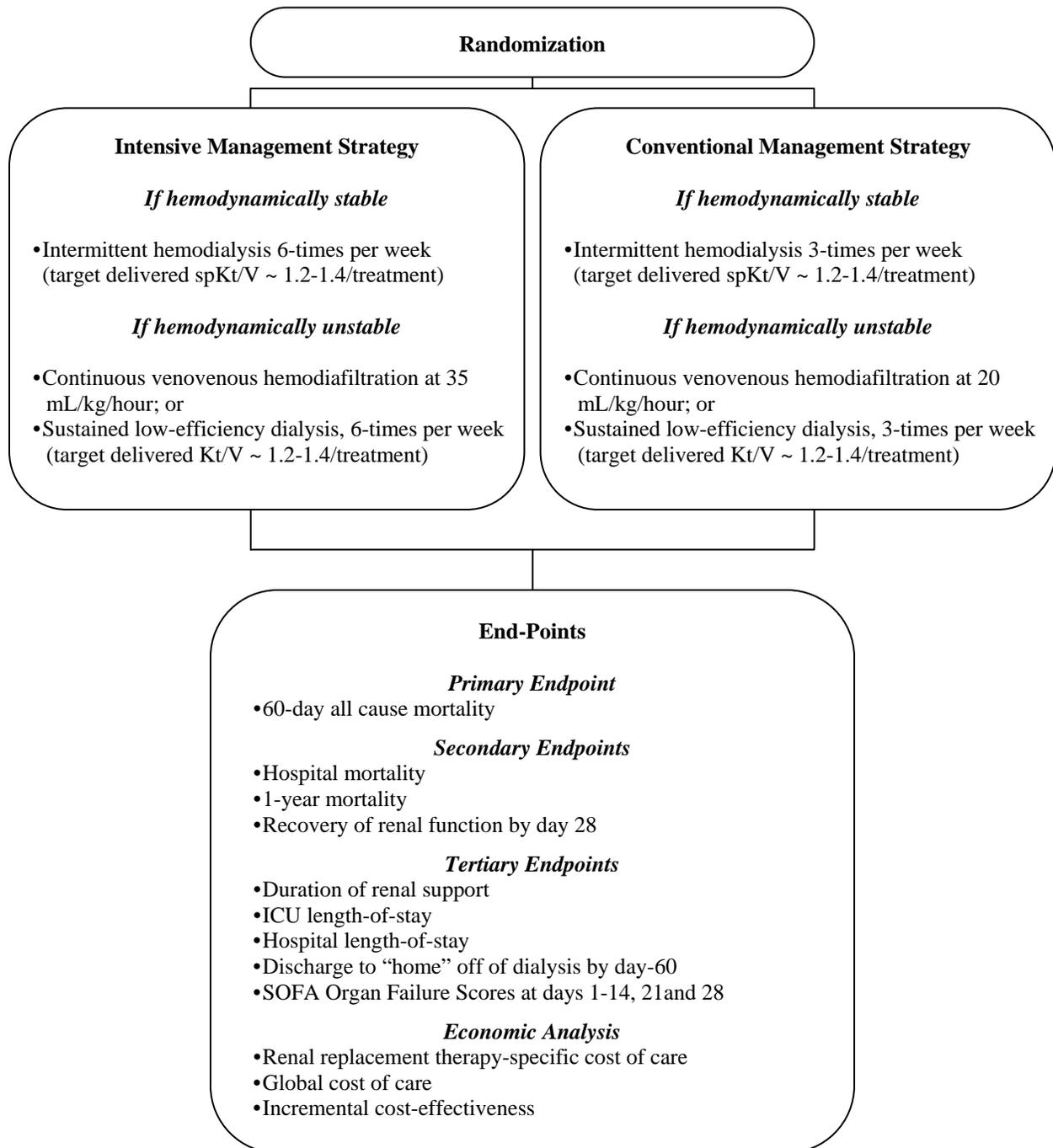
### Study Sites

- 18 VA Sites (9 patients/year)
- 9 Non-VA sites (28 patients per year)

### Study Duration

- 3-years enrollment
- 60 days maximum primary follow-up

## Overview of Study Design (continued)



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### **III. STUDY ADMINISTRATION, ORGANIZATION, AND PERSONNEL**

#### **A. Study Administration and Organization**

The West Haven Cooperative Studies Coordinating Center, the Study Chairman, and NIDDK will administer the trial and oversee its organization.

##### **1. Monitoring Bodies**

The groups charged with monitoring the various aspects of the study will be the Executive Committee, the Data and Safety Monitoring Board, the Human Rights Committee and the Study Group. These committees will meet at regular intervals according to the Cooperative Studies Program guidelines. These committees will meet prior to the beginning of patient intake, six to nine months later and every twelve months thereafter. In addition, at the midpoint of the study, the Cooperative Studies Evaluation Committee (CSEC) will monitor and review the progress of the study.

The Executive Committee, the management and decision-making body for the operational aspects of the study, will monitor the performance of participating medical centers and the quality of data collected. The Executive Committee will formulate publication plans and oversees the publication and presentation of all data from the study. The Committee must grant permission before any study data may be used for presentation or publication.

The Data and Safety Monitoring Board (DSMB) will review the progress of the study and will monitor patient intake, outcomes, adverse events, and other issues related to patient safety. The DSMB has the capacity to make recommendations to the Chief of the Cooperative Studies Program about whether the study should continue or be stopped. The DSMB may consider safety or other circumstances as grounds for early termination, including either compelling internal or external evidence of treatment differences or lack of feasibility of addressing the

study hypothesis (e.g. poor patient intake, poor adherence to protocol). The Study Biostatisticians will provide data to the DSMB at intervals specified by the Board as suggested in the study protocol.

The Human Rights Committee (HRC) at the Coordinating Center will review the study annually to ensure proper protection of patients' rights and safety. The Study Chairman and the Study Biostatisticians will present the HRC with a report about the progress of the study and ethical issues relevant to the HRC. In the interim, the HRC may be asked to convene if there is any serious adverse event requiring its attention. An HRC member will regularly attend each meeting of the DSMB and a member will site-visit at least one center annually to determine that the patients' rights and safety are being properly protected.

The Study Group, which consists of all participating investigators and coordinators, will meet annually to discuss the progress of the study and any problems encountered during the conduct of the trial. No endpoint data will be presented to this group.

## **2. Monitoring Patient Intake/Probation, Termination of Participating Sites**

The Study Chairman and the Study Biostatisticians will monitor the intake rate and operational aspects of this study. Participating medical centers will continue in the study only if adequate patient intake is maintained. Actions leading to discontinuation of patient enrollment at a center will only be taken by the Executive Committee with the concurrence of the DSMB and Chief, CSP.

If recruitment is not proceeding at an appropriate rate, the Study Chairman and the Study Biostatisticians will scrutinize the reasons for patient exclusion. Based on this information the Executive Committee may choose, with the approval of the Data and Safety Monitoring Board

and Chief, CSP, to drop centers or add additional centers, or to make minor modifications to the inclusion/exclusion criteria.

### **3. Study Sites and Patient Accrual**

The 18 participating VA and nine participating non-VA sites and their personnel are listed in the personnel directory in Part B of this section.

a. Accrual at VA Sites – A total of 18 VA sites are participating in this study. Each VA site is expected to enroll a total of 27 patients during the three-year enrollment period of this study, averaging 9 patients enrolled per site per year. Sites that do not enroll at least 3 patients during the first 6 months of their participation in the study will be given an opportunity to improve within a reasonable period of time. If there is no improvement in accrual after a predetermined period of time, the site may be subject to reduced funding or possible termination as a study site. In the event that the site is terminated, support will be provided for the follow-up of any patient already enrolled at that site.

b. Accrual at Non-VA Sites – A total of nine non-VA sites are participating in this study. Each non-VA site is expected to a total of 84 patients during the three-year enrollment period of this study, averaging 28 patients enrolled per site per year. Sites that do not enroll at least 9 patients during the first 6 months of their participation in the study will be given an opportunity to improve within a reasonable period of time. If there is no improvement in accrual after a predetermined period of time, the site may be subject to reduced funding or possible termination as a study site. In the event that the site is terminated, support will be provided for the follow-up of any patient already enrolled at that site.

#### **4. Monitoring Medical Center Performance**

Strict adherence to the protocol will be expected of every participating center and will be monitored by the Data and Safety Monitoring Board, the Executive Committee and the Study Group. Documentation of protocol breaches will be required and any medical center with repeated protocol violations will be recommended to the Data and Safety Monitoring Board for termination. If a participating site investigator feels that adherence to the protocol will in any way be detrimental to a particular subject's health or well-being, the interest of the patient must take precedence. By agreeing to participate in this study, the medical center delegates responsibility for global monitoring of the ongoing study to the Data and Safety Monitoring Board, the Cooperative Studies Program Coordinating Center's Human Rights Committee, the Cooperative Studies Evaluation Committee, and the West Haven Cooperative Studies Program Coordinating Center. However, the Research and Development (R&D) and the Human Studies Subcommittee (IRB) at VA medical centers and the IRB at non-VA sites will require the participating investigators to submit reports at least annually concerning the status of the study at the site for local monitoring purposes.

#### **5. Site Visits**

Site visits by the Study Chairman, the Study Biostatisticians, the Site Monitoring And Review Team (SMART), or other technical experts are not a routine part of Cooperative Studies Program (CSP) studies, but may be required in certain cases. In the event a site visit occurs, the site report is then sent to the Executive Committee and Director, CSPCC for appropriate action.

Monitoring of sites participating in the VA/NIH ATN Trial will be executed according to Cooperative Studies Program (CSP) Guidelines. Consistent with current CSP policy, VA personnel will make site visits to participating sites during the course of the study. The purpose

of these visits is to encourage and assess compliance with Good Clinical Practice requirements. Reviewers will examine patient study files including source documents in both clinic (study) files and patients' official site medical records and will also review regulatory/essential documents such as IRB correspondence and FDA regulatory documents. Areas of particular concern will be patient informed consent issues, protocol adherence, safety monitoring, IRB reviews and approvals, regulatory documents, patient records, and site operations/investigator involvement.

## **6. Data and Safety Monitoring Board**

As mentioned above, the VA/NIH ATN Study will be overseen by an independent Data and Safety Monitoring Board, which in addition to seeing that the trial is being conducted in the manner proposed, will be responsible for the ethical conduct of the study. This committee will consist of expert nephrologists, intensivists, and at least one biostatistician and one health economist. These experts will not be participants in the trial and will not have participated in the review process of the protocol. This committee will make recommendations to VA Chief Research and Development Officer (CRADO) regarding the continuation or discontinuation of the trial. The DSMB will meet at least annually, and may have semi-annual conference calls, which will be arranged by the study Chairman and the Study Biostatisticians.

At each of its meetings during the study period, the DSMB will review the randomization rates and assess the difference between the actual and the projected rates, as well as the impact of these assessments on overall trial size. If the enrollment is inadequate, the reasons for exclusions may be scrutinized and actions may be suggested. An assessment of whether the trial should be continued will be made followed by a recommendation, as appropriate.

Two interim looks at the primary study endpoint will be proposed to the DSMB. It will be proposed that the first interim analysis be done when at least 600 subjects have been enrolled and followed for more than 60 days and the second interim analysis be done when at least 900 subjects have been enrolled and followed for more than 60 days. Conditional power to detect the hypothesized effect will also be provided to the DSMB at the time of the two interim analyses. Trial safety will be monitored by CSPCC and reported to the DSMB after enrollment and 60-day follow-up of each 200 patient block (i.e., after 200, 400, 600, 800, and 1000 patients), or every 6 months, whichever comes first. Serious adverse events will be reported to the DSMB on an on-going basis.

**B. Directory of Study Participants**

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**B. Directory of Study Participants (cont'd)**

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**B. Directory of Study Participants (cont'd)**

**Site No. Site Address**

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**B. Directory of Study Participants (cont'd)**

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**B. Directory of Study Participants (cont'd)**

**Site No. Site Address**

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**B. Directory of Study Participants (cont'd)**

**Site No. Site Address**

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**B. Directory of Study Participants (cont'd)**

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**B. Directory of Study Participants (cont'd)**

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**Site No. Site Address**

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### **C. Change Of Site Personnel Form**

Changes in personnel must be communicated in a timely manner to West Haven CSPCC. A Change of Site Personnel Form must be completed when there is a change of site personnel. A sample of this form is shown on the following page.

Whenever there are changes in your mailing address, email address, telephone number, participating investigator or nurse coordinator please complete this information form. This information is needed for administrative purposes such as funding, publications, etc. Please check the appropriate boxes and print clearly.

Investigators must have approval from Chairman's Office. A 1572 form with PI's CV should be sent to Albuquerque Pharmacy.

**WEST HAVEN COOPERATIVE STUDIES PROGRAM**  
**CSP #530- ATN**  
**CHANGE OF SITE PERSONNEL**

*This information is needed for administrative purposes (funding, publications)*

**VAMC:** \_\_\_\_\_ **Site #** \_\_\_\_\_ **Date:** \_\_\_/\_\_\_/\_\_\_

**Please check the appropriate box and print clearly.**

Participating Investigator

**Investigators must have  
Approval from Chairman's  
Office. Also, 1572 with CV to  
Albuquerque Pharmacy**

**Current:** \_\_\_\_\_ **Start Date:** \_\_\_/\_\_\_/\_\_\_

**Name:** \_\_\_\_\_ **SS#:** \_\_\_\_-\_\_\_\_-\_\_\_\_  
Last First Title

**Address:** \_\_\_\_\_ **E-mail:** \_\_\_\_\_

**Section Title:** \_\_\_\_\_

**Phone:** ( ) \_\_\_\_\_ **FAX:** \_\_\_\_\_

**Previous:**

**Name:** \_\_\_\_\_ **Ending Date** \_\_\_/\_\_\_/\_\_\_  
Last First Title

Study Coordinator

**Current:** \_\_\_\_\_ **Start Date:** \_\_\_/\_\_\_/\_\_\_

**Name:** \_\_\_\_\_  
Last First Title

**Address:** \_\_\_\_\_ **E-mail:** \_\_\_\_\_

**Phone:** ( ) \_\_\_\_\_ **FAX:** \_\_\_\_\_

**Previous:**

**Name:** \_\_\_\_\_ **Ending Date** \_\_\_/\_\_\_/\_\_\_  
Last First Title

**FAX Form to (203) 937-3858 or Send Original to:**

*(Include copy of Human Subjects Training Certificate,  
as well as HIPAA and GCP Training Certificates)*

Thomas Roy, Project Manager  
VAMC-CSPCC (151A) Bldg 35  
950 Campbell Avenue  
West Haven, CT 06516

#### **IV. GOOD CLINICAL PRACTICES**

##### **A. Cooperative Studies Program Policy**

This trial will be conducted in compliance with Good Clinical Practice regulations (GCP). The intent of these regulations is to safeguard subjects' welfare and assure the validity of data resulting from the clinical research. The VA Cooperative Studies Program will provide manuals and materials to assist study sites in organizing study files and will be available throughout the trial to advise and assist investigators regarding GCP issues.

Materials provided by include:

Essential Documents Binder (1 per site)  
Patient Binders (1 per patient)  
Source Document Guide (electronic document)

## **B. Investigator Study File (Content and Organization)**

The Investigator Study File consists of all records and materials at the participating study site pertaining to the study. This includes patient files (both case report forms and supporting medical records) and other study-related correspondence and documents often referred to as the “regulatory” documents.

### Investigator Study File

1. Protocol
2. Protocol Amendments
3. Supplemental Protocol Instructions (Operations Manual, etc.)
2. Case Report Forms
3. Investigator Brochure
4. Consent Form/Patient Information/Advertising
5. Subject Log (all screened/consented patients)
6. Serious Adverse Events / Safety Reports
7. IRB Correspondence
10. Site-Sponsor Correspondence
11. Other Correspondence / Notes-to-File
12. Telephone / Communications Log
13. Clinic Staff - Roles and Responsibilities/Signatures
14. Investigational Product Accountability
15. Regulatory Documents
16. Individual Patient Records and Source Documents

The investigator’s study records must be complete, well organized, readily identifiable and accessible. To help sites develop study files meeting these requirements, CSP will provide an Essential Documents Binder, individual patient binders and source document guidance specifying acceptable source documentation for each data collection form.

### **C. Essential Documents Binder**

Each participating site will receive a specially prepared binder to aid in organizing the Investigator Study File, i.e., all records and documents related to the trial. It is neither intended nor possible to place the entire Investigator Study File in the Essential Documents Binder, but rather this binder is to serve as a directory to all the study documents and records in the study clinic/study office and as a repository for those items that can be accommodated in the binder. Obviously, due to space limitations certain documents may need to be filed elsewhere with a note of explanation placed in the appropriate section of the binder to note the location.

The Study Coordinator will be responsible for maintaining the Essential Documents Binder and should make it readily accessible to all study staff. The binder should be updated throughout the course of the trial, but it is essential that it be updated and current at the time of study closure.

### **D. Patient Study File (Clinic File)**

GCP requires that investigators keep adequate and accurate case histories for study subjects. The case history, also called the patient study file, consists of 1) the case report forms as provided by the CSPCC and 2) the supporting source documents in the patient's medical record and/or clinic file. At VA sites, the original of the signed informed consent and the signed re-consent must also be filed in the patient study file, with a copy filed in the patient's medical record. At non-VA sites, the original or a copy of the signed informed consent and the signed re-consent must be filed in the patient study file and the patient's medical record, as consistent with current policy at the participating non-VA site. Because some of the source documents in CSP trials may be part of the official medical record of the patient, not all source documents can be

retained under the personal control of the investigator. They are nonetheless considered a part of the Investigator Study file and must be linked to the other records in the investigator's possession by methods explained below. Conversely, some study documents are not appropriate for inclusion in the medical record and will be retained in the investigator's possession.

### **1. Individual Patient Binders**

Binders with labeled dividers will be supplied to serve as the central element in organizing the patient study file. The Study Coordinator will be responsible to establish and maintain a patient binder and additional folders or binders as may be needed to hold the study documents for the patient. The patient binder shall contain copies of the case report forms, patient locator information (address, etc.), and, at VA sites, the original signed consent/re-consent form. At non-VA sites, the original signed consent/re-consent form, or a copy, as consistent with current policy at the participating non-VA site, is stored in the patient binder. Source documentation as described below can also be placed in the binder. The Study Coordinator must assure that study-related records generated by the Investigator or other study personnel are incorporated into the patient binder or associated folders during the trial (or upon study closure, if more consistent with clinic logistics and operations).

### **2. Source Documentation**

In addition to retaining copies of the case report forms in the patient file, documentation of the source of the data must also be maintained. The patient study file either must contain the source documents for the CRF data or must provide a clear indication of where the source documentation can be found. This practice assures compliance with the requirement that supporting documents be readily identifiable and accessible.

Ideally, every data point recorded on the CRF will have a supporting “original” entry recorded first in the medical record or other notes, worksheets, logs, etc. For the patient-completed or phone-administered instruments, recording directly onto the CRF is unavoidable and in such instances the CRF is also serves as the source document. Supporting documentation would consist of only the progress note declaring that the patient was called and the patient or his/her proxy completed the instrument per protocol. A table describing acceptable source documentation for each data form will be included in the example *Study Patient Binder* to be provided to each site. This table will also list those study forms upon which study data may be recorded directly.

A source document template/directory will be provided by CSP for use by sites to generate source documents or, alternatively, to indicate where the source documents are located in the medical record. The chart given at the end of this section indicates source documents for each study CRF. While not mandatory, it is an advisable practice to insert into the patient file copies of any source documentation found in the patient’s medical record.

In addition to supporting and allowing verification of the CRF data, source documentation should document the progress of the patient through the trial. As a minimum, a progress note should be written for each contact with the patient. Included in the progress notes should be information on adverse events, patient compliance with instructions, telephone contacts and any study data not recorded elsewhere in the medical record or other original record. The investigator is encouraged to write progress notes, but at a minimum should co-sign or otherwise acknowledge those of the Study Coordinator and other study staff.

## **E. IRB-Investigator Interactions**

CSP must rely on each investigator to assure that the IRB operates in compliance with GCP regulations and that the trial is appropriately reviewed. Before initiating the trial, the investigator presents the protocol and consent form to the R&D Committee and its IRB for review, revising the prototype consent form provided in the protocol as necessary to meet institutional requirements. The investigator must resubmit the protocol for review annually or more often if required by the IRB. Additionally, the investigator must report to the IRB all unexpected risks to patients (e.g., serious adverse events), proposed recruitment advertising and proposed protocol changes. Deviations from the protocol, whether approved or unapproved, do not constitute protocol changes but must be reported to the IRB if they represent unanticipated risks. CSP may advise investigators of items requiring IRB review, but it is the investigator's responsibility to determine what items need to be reported to or approved by his or her local IRB.

## **F. Patient Informed Consent**

The investigator is responsible to assure that patient or surrogate (if the patient lacks decision-making capacity) consent is obtained and documented as described in the study protocol and the operations manual (see Section VI of the Operations Manual). The patient/surrogate will be given a copy of the consent form. At VA sites, the original signed consent form will be filed in the patient's study binder. At non-VA sites, the original signed consent form, or a copy, as consistent with current policy at each participating non-VA site, will be filed in the patient's study binder. A signed, dated and timed progress note must be written in the patient's medical record to document that the patient or the patient's surrogate provided consent before study participation.

## **G. Archiving Study Records**

At the close of the trial, investigators will be instructed in the requirements for record retention. At that time, the study coordinator or investigator should assure that all patient records generated by any member of the study team are combined with those maintained by the coordinator. The Essential Documents Binder should be reviewed and updated as study records are prepared for storage so that this binder can accurately serve as a directory to all study documents in the archived Investigator Study File. Source documents as well as the investigator's copies of the CRFs must be retained for a minimum of five years following completion of a CSP trial, or longer if local institutional policy requires. If storage of study records becomes a problem at any time during or following study completion, CSPCC should be contacted concerning alternative provisions for records storage or disposal. **NEVER DESTROY STUDY RECORDS WITHOUT CSPCC AUTHORIZATION.**

**FORMS COMPLETION AND SOURCE DOCUMENTATION**  
**RECOMMENDED PRACTICES FOR CSP #530**

<b>Case Report Form</b>	<b>Completed By</b>	<b>Source Document*</b>
01 Screening/Eligibility	Study Coordinator	Progress Note <sup>®</sup> supplemented by history & lab results from medical record and by source documentation worksheets created for patient file
02 Informed Consent Form - VA Form 10-1086 or non-VA	Study participant, research team members	The form itself * & Progress Note
02T Cover sheet-attach to Consent Form (2)	Study Coordinator	The form itself *
02A Informed [RE-] Consent - VA Form 10-1086 or non-VA	Study participant, research team members	The form itself * & Progress Note
02R Cover sheet - attach to Re-Consent Form	Study Coordinator	The form itself *
03 Randomization Form	Study Coordinator ♦	Progress Note + (confirm eligibility)
04 Baseline Data Form	Study Coordinator	Diagnosis, H&P, and nutrition data from medical record and patient interviews (worksheet recommended)
05 Subject Contact Form	Study Coordinator	The form itself *
06 Baseline Score and Laboratory Values	Study Coordinator	ICU/respiratory flow sheets, I&O report, lab reports, note for Glasgow (worksheet recommended for these)
07 Study Day Scores and Laboratory Values	Study Coordinator	Same as for Form 06
08 Medication Form	Study Coordinator	Medication administration record at day 7 plus discharge summary day 28
09 Renal Replacement- Each Treatment	Study Coordinator	Dialysis/ICU flow sheets and, if complications, Progress Note (log is recommended for patient study file)
10 Discontinuation Study Therapy	Study Coordinator ♦	Progress Note
11 Day 28 Post Randomization Status Form	Study Coordinator	Progress Note, laboratory results and, if applicable, discharge summary
12 Day 60 Post Randomization Status Form	Study Coordinator (often phone)	Progress Note, laboratory results and, if applicable, discharge summary
13 Study Exit Form	Study Coordinator ♦ (often phone)	Progress Note
14 Release of Information Form	Study Coordinator	The form itself*
15 Catheter Insertion Form	Study Coordinator	Progress Note (log is recommended)
16 Serious Adverse Event Form	Study Coordinator ♦	Progress Note and relevant medical record entries
17N 60 day Follow up for Non-VA patients	Study Coordinator (phone)	The form itself and Progress Note documenting the telephone interview
17V 60 Day Follow up for VA Subjects	Study Coordinator (phone)	The form itself and Progress Note documenting the telephone interview
18N 12 month Follow-up for Non-VA Subjects	Study Coordinator (phone)	The form itself and Progress Note documenting the telephone interview
18V 12 month Follow up for VA Subjects	Study Coordinator (phone)	The form itself and Progress Note documenting the telephone interview
19S, 19P Health utilities Index	Study Coordinator (phone)	The form itself and Progress Note documenting the telephone interview
20N Diary for Non-VA Subject Use	Study participant	Not a CRF-will not be returned to site
20V Diary for VA Subject Use	Study participant	Not a CRF-will not be returned to site
21 Biorepository Specimen Confirmation	Study Coordinator	Common log for all patients noting dates of sample collections

- @ Progress Notes - All contacts with study patients, including telephone calls, should be documented in progress notes written by the coordinator or investigator and should be supplemented whenever applicable by progress notes of other care providers and other items from the medical record as may be relevant (e.g., laboratory reports). Progress notes documenting patient contacts and the patient's progress through the trial can be very brief if supplemented by additional source documentation appearing in the medical record or captured in specially designed source document worksheets placed in the patient's study file. Progress notes generated for trial purposes should be incorporated into the patient's official medical record whenever inclusion is appropriate. It is highly recommended that progress notes written by the coordinator or other study team members be co-signed or acknowledged by the investigator.
- \* An entry of "the form itself" in this column indicates that Information is recorded directly onto the data form. The progress note generated for each patient visit or contact should document completion of such forms as well as completion of other required study tasks.
- ◆ Assisted by the investigator
- + The randomization note should include a specific statement that the subject qualifies for study participation based on history and current health status. This note should be written or co-signed by the investigator.

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## **V. PATIENT SCREENING AND RECRUITMENT**

A key requirement for the success of this trial will be the efficient identification and enrollment of patients. Our target enrollment is 1164 patients over 36 months or approximately 33 patients per month. The 18 VA sites have a target enrollment of just under 1 patient per month (9 patients per year), while the 9 non-VA sites have a target enrollment of just over 2 patients per month (28 patients per year). It is our expectation that only one-third of patients identified as eligible for the study will ultimately be randomized. There are a multitude of reasons – including patient/surrogate refusal to participate, inability to locate the appropriate surrogate decision-maker for the informed consent process (see Section VI) and resistance from the primary treatment team to protocolized management of renal replacement therapy. It is therefore critical that each site develops an effective strategy to identify all potential candidates for this study. Potential strategies will need to be individualized for each institution but might include daily review of potential patients with ICU staff, the renal consult service or review of patient data using computerized medical record systems.

### ***Ethical Conduct of Patient Screening***

While patient enrollment is of paramount importance for the success of this study, zeal in identifying patients must be tempered by the need to respect patient privacy and adhere to local rules established by your IRB. Two key issues may arise in this regard: 1) under HIPAA, access to protected health information (PHI) may require either explicit patient consent or a waiver of consent for screening provided by your institution's IRB/Privacy Board; and 2) the initial discussion of the study with a potentially eligible patient (or surrogate decision-maker) may need to be made by a member of the treatment team.

### Waiver of Authorization

In order to comply with HIPAA, consent must be provided prior to obtaining any information about a patient – including the patient’s name. Although some institutions have adopted an approach of having patients sign a blanket consent to permit access to PHI for research purposes, other institutions have taken a far more restrictive approach, requiring specific consent prior to review of patient records for screening. This obviously poses a significant problem since there is no way to obtain consent if access to data to identify patients appropriate for screening is prohibited. If your institution has adopted these restrictive rules, one solution is to obtain a “waiver of authorization” from your IRB or Privacy Board for the screening process. Waiver requests must be submitted and approved in writing prior to initiating screening. A request for waiver of authorization must satisfy all of the following criteria:

- The research could not feasibly be conducted without the waiver;
- The research could not feasibly be conducted without access to the protected health information (PHI);
- The use or disclosure of the protected health information involves no more than minimal risk to a subject’s privacy and includes a plan to protect identifiers, a plan to destroy identifiers at the earliest opportunity and assurance that the PHI will not be reused;
- The rights or welfare of the subject will not be adversely affected by the waiver; and
- The risks posed by the waiver of authorization are reasonable in relation to the anticipated benefits of the research.

Each study site is responsible for ensuring that they have obtained any necessary approvals for screening subjects and must provide a copy of the approved plan for patient

screening (including any “waiver of authorization”) to the West Haven CSPCC prior to study initiation.

### Contacting Potential Study Subjects

Contacting potential subjects without prior introduction to the patient by a member of the treatment team may be prohibited by local IRB rules as a form of “cold calling”. Strictly speaking, “cold calling” is when research staff who are not known to the potential research subject initiate telephone contact with the subject to solicit their participation in a research study based on knowledge of the subject’s PHI without prior introduction to or permission from the subject. To avoid a “cold-calling” scenario, an individual who is a member of the patient’s treatment team should initially introduce the research study to the potential research subject/surrogate decision-maker and request permission to have you or another member of the research team contact them. This permission does not need to be more than a verbal assent to being contacted. This prohibition does not apply if you or another member of the research team are also a member of the treatment team and have an established caregiver relationship with the patient/surrogate decision-maker.

### ***Inclusion Criteria***

The specific inclusion criteria for the study, along with their operational definitions, are listed in Table 2. The target population for the study consists of critically ill patients with acute renal failure due to acute tubular necrosis who require renal replacement therapy. For the purpose of the study acute renal failure is defined as ***either***:

- An increase in serum creatinine of 1.5 mg/dL in women or 2 mg/dL in men over a period of no more than 4 days; or
- Oliguria (an average urine output  $\leq$  20 mL/hour) for more than 24 hours.

Uncomplicated acute renal failure may be associated with mortality rates of < 10%, while acute renal failure in the ICU setting has been associated with mortality rates of 50-70%, or higher. It is in this latter population that the intervention of more intensive renal support is most likely to improve outcomes. For this reason, the presence of at least one non-renal organ system failure (defined based on a SOFA organ system score of  $\geq 2$ , see table 1) or the presence of severe sepsis is an additional inclusion criterion.

The decision to initiate renal replacement therapy is not dictated by the study protocol. There are no precise, generally accepted, clinical criteria for the initiation of renal replacement therapy in patients with acute renal failure. The initiation of renal replacement therapy should therefore be based on the clinical expertise of the clinical treating service. For the purpose of this study, the following criteria are appropriate indications for initiation of renal replacement therapy in ARF:

- Volume overload
- Persistent hyperkalemia
- Severe metabolic acidosis
- Uremic signs and/or symptoms
- BUN  $\geq 40$  mg/dL in the absence of other specific indications

***The decision to initiate RRT is a specific inclusion criterion and must be made by the primary treatment team prior to study enrollment.***

Patients must be at least 18 years of age. Informed consent must be provided by the patient or by a surrogate decision-maker if the patient lacks decision-making capacity (see section VI).

### ***Exclusion Criteria***

The exclusion criteria for the study, along with their operational definitions, are detailed in Table 3. Patients with underlying chronic kidney disease, defined as a baseline serum creatinine of > 2 mg/dL in males and > 1.5 mg/dL in females, will be excluded since the natural history of acute-on chronic kidney disease may be different than ARF in patients without underlying kidney disease. ***In patients in whom prior medical information is not available, the absence of CKD will be inferred if a) there is no medical history of kidney disease and b) there are no changes of CKD on renal ultrasound.***

Patients with ARF due to etiologies other than acute tubular necrosis will also be excluded from the study. A precise diagnosis of the etiology of ARF is often difficult and is generally made on the basis of imprecise clinical criteria. Clinical criteria to suggest diagnoses of ARF other than ATN are provided in Table 4. The presence or absence of any of these clinical diagnoses should be determined based on the consensus of the treating clinical team and the nephrology site investigator.

Patients in whom there has been undue delay in initiation of renal replacement therapy will also be excluded from the study as there is data to suggest that delayed initiation of renal support in ARF may be associated with increased mortality risk. Thus, patients who have met the definition of ARF, as specified in the inclusion criteria, for more than 72 hours and have had a BUN greater than 100 mg/dL for more than 72 hours duration will be excluded from the study. For patients who present to the hospital with ARF and a BUN > 100 mg/dL, this 72-hour interval begins at the time of hospitalization.

Patients will not be eligible for enrollment in the study if they have received more than 1 hemodialysis or SLED treatment or more than 24 hours of CRRT for this episode of ARF prior

to randomization. Patients developing ARF following kidney transplantation are not eligible for the study. Due to difficulty in delivering the target dose of therapy, patients with pre-morbid weights of greater than 128.5 kg (282.5 lb) will also be excluded.

Patients with known pregnancy will also be excluded. Acute renal failure in pregnancy is usually due to etiologies other than ATN, such as preeclampsia, HELLP syndrome and hemolytic uremic syndrome. In addition, by analogy with data from pregnancy in patients with CKD, patients with late-gestation pregnancy have better outcomes with intensive dialysis. Randomization to the conventional therapy arm would therefore be unethical. The necessity for serologic pregnancy testing is debatable. Urine pregnancy tests may be unreliable in the setting of renal failure. Pregnancy testing in fertile women with ARF in whom pregnancy is not suspected is not usually performed, and these patients would normally be treated with conventional management. While not required by the protocol, serum pregnancy testing to identify unsuspected pregnancy may be required by individual IRBs

Prisoners will not be eligible for participation in the study. Patients who are not candidates for renal replacement therapy based on patient preference, decision of surrogate decision-maker if patient lacks decision-making capacity or primary treating team will be excluded from the study. Similarly, patients who are moribund and are not expected to survive more than 24 hours regardless of therapy, patients in whom the goals of therapy are comfort only and patients who are not expected to survive 28-days because of an irreversible *chronic* medical condition (e.g., end-stage malignancy) are not candidates for the study. Patients may not be enrolled in the study if they are already participating in an interventional study (although patients may participate if they are enrolled in an observational study), if the patient (or surrogate

decision-maker if patient lacks decision-making capacity) refuses to consent to participate, or if the primary treating team objects to patient participation in the study.

**Table 1**

	<b>SOFA Sequential Organ Failure Score</b>				
	0	1	2	3	4
Respiratory					
Pao <sub>2</sub> /Fio <sub>2</sub> (mmHg)	>400	≤400	≤300	≤200 <sup>a</sup>	≤100 <sup>a</sup>
Coagulation					
Platelets (x 10 <sup>3</sup> /μL)	>150	≤150	≤100	≤50	≤20
Liver					
Bilirubin (mg/dL)	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12.0
Cardiovascular					
MAP (mm Hg)	MAP ≥70	MAP <70			
Pressors <sup>b</sup> (doses in mcg/kg/min)	None	None	Dopamine ≤5 or Dobutamine (any dose)	Dopamine >5 or Epinephrine ≤0.1 or Norepinephrine ≤0.1	Dopamine >15 or Epinephrine >0.1 or Norepinephrine >0.1 or Vasopressin (any dose)
Central Nervous System					
Glasgow Coma Score	15	13-14	10-12	6-9	<6
Renal					
Creatinine (mg/dL)	<1.2	1.2-1.9	2.0-3.4	3.5-4.9 or	≥5 or
Urine output (mL/day)				<500	<200

<sup>a</sup>. Values are with ventilatory support; the maximum score in patients not receiving ventilatory support is 2

<sup>b</sup>. Pressor agents administered for at least 1 hour

**Table 2**

<b>Inclusion Criteria</b>	
<b>Criterion</b>	<b>Definition</b>
<p>Acute renal failure clinically consistent with a diagnosis of acute tubular necrosis, defined as: Clinical setting of ischemic or nephrotoxic injury</p> <p style="text-align: center;">AND</p> <p>Oliguria (average urine output &lt; 20 mL/hour) for &gt;24 hours or An increase in serum creatinine of <math>\geq 2</math> mg/dL (<math>\geq 1.5</math> mg/dL in females) over a period of <math>\leq 4</math> days</p>	<p>ARF developing in the setting of and attributed to:</p> <ol style="list-style-type: none"> <li>1. Hypotension with MAP &lt; 60 mmHg;</li> <li>2. Pressor administration (dopamine &gt; 5 mcg/kg/min or any dose of norepinephrine, epinephrine, phenylephrine or vasopressin);</li> <li>3. Recent cardiac, abdominal or vascular surgery;</li> <li>4. Severe sepsis (defined a bacteriologically proven or suspected infection with evidence of systemic inflammation or organ dysfunction)</li> <li>5. Rhabdomyolysis;</li> <li>6. Intravascular hemolysis;</li> <li>7. Administration of intravenous or intra-arterial radiocontrast; or</li> <li>8. Administration of known nephrotoxic agents (e.g., aminoglycosides, amphotericin B, acetaminophen)</li> </ol> <p>1. Urine output of &lt; 480 mL over 24 hours period 2. Absence of volume contraction</p> <p>1. Increase in serum creatinine of:     <math>\geq 2</math> mg/dL in males, or     <math>\geq 1.5</math> mg/dL in females over a period of <math>\leq 4</math> days. 2. If no recent baseline serum creatinine is available (e.g., patient with no past history of CKD* but admitted with established ARF) assume baseline serum creatinine of:     2.0 mg/dL in males, or     1.5 mg/dL in females</p>
<p>Plan for renal replacement therapy by the clinical team</p>	<p>Clinical treatment team (e.g., nephrology, critical care or primary service) has made decision that patient requires initiation of renal replacement therapy</p>
<p>Receiving care in critical care unit (e.g., MICU, SICU, CCU)</p>	<p>Patient is being treated in a critical care unit</p>

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**Inclusion Criteria**

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<b>Criterion</b>	<b>Definition</b>
One non-renal organ failure (SOFA organ system score $\geq 2$ ) or the presence of sepsis	One or more of the following is documented: <ol style="list-style-type: none"> <li>1. <math>\text{PaO}_2/\text{FiO}_2 \leq 300</math> mmHg;</li> <li>2. Platelet count <math>\leq 100,000</math> mm<sup>3</sup>;</li> <li>3. Bilirubin <math>\geq 2.0</math> mg/dL;</li> <li>4. Hypotension (MAP <math>&lt; 70</math> mmHg) requiring any pressor support;</li> <li>5. Glasgow Coma Scale <math>\leq 12</math>; or</li> <li>6. Serious infection (bacteriologically proven or suspected) with evidence of systemic inflammation or organ dysfunction<sup>#</sup></li> </ol>
Age $\geq 18$ years	Age $\geq 18$ years
Patient/surrogate willing to provide informed consent	<ol style="list-style-type: none"> <li>1. Patient with decision-making capacity and willing to provide informed consent, or</li> <li>2. Patient lacks decision-making capacity, legally appropriate surrogate decision-maker willing to provide informed consent</li> </ol>

\*absence of objective evidence of CKD needs to be sought, including documentation of a renal ultrasound demonstrating normal renal architecture without increased echogenicity or decreased renal size.

<sup>#</sup>The 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference concluded that the SIRS criteria were overly sensitive and non-specific and proposed a definition of documented or suspected infection associated with evidence of systemic inflammation or organ dysfunction. Severe sepsis was defined as sepsis associated with organ failure. Since all patients eligible for the study have ARF, all patients with sepsis meet the definition for severe sepsis.

**Table 3**

<b>Exclusion Criteria</b>	
<b>Criterion</b>	<b>Definition</b>
Baseline serum creatinine > 2 mg/dL (> 1.5 mg/dL in females)	<ol style="list-style-type: none"> <li>0. Documented baseline serum creatinine greater than:               <ol style="list-style-type: none"> <li>2.0 mg/dL in male patients</li> <li>1.5 mg/dL in female patients</li> </ol> </li> <li>1. In the absence of available documentation of prior serum creatinine, there must be a lack of a history of chronic kidney disease and documentation of a renal ultrasound demonstrating normal renal architecture without increased echogenicity in order to assume that the baseline serum creatinine are not greater than the above limits</li> </ol>
Acute renal failure clinically believed to be due to an etiology other than ATN	See Table 4
More than 72 hours since meeting both of the following conditions: <ul style="list-style-type: none"> <li>• Fulfillment of the definition of ARF; and</li> <li>• BUN &gt; 100 mg/dL</li> </ul>	<ol style="list-style-type: none"> <li>1. More than 72 hours since both of the following have been present:               <ol style="list-style-type: none"> <li>a. definition of ARF as detailed in the Inclusion Criteria; and</li> <li>b. BUN &gt; 100 mg/dL</li> </ol> </li> <li>2. For patients who present to the hospital with ARF and a BUN &gt; 100 mg/dL, more than 72 hours since hospital admission</li> </ol>
More than 1 hemodialysis treatment or > 24 hours since starting CRRT	<ol style="list-style-type: none"> <li>1. More than 1 hemodialysis treatment performed prior to enrolling patient;</li> <li>2. More than 1 SLED treatment performed prior to enrolling patient; or</li> <li>3. Greater than 24 hours since initiation of CRRT prior to enrolling patient</li> </ol>
Prior kidney transplant	Acute renal failure in a patient with a previously functioning renal allograft
Pregnancy	<ol style="list-style-type: none"> <li>1. Clinical history of pregnancy; or</li> <li>2. Physical examination consistent with pregnancy</li> </ol>
Prisoner	Status as prisoner
Weight > 128.5 kg	Pre-morbid, edema-free weight > 128.5 kg

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**Exclusion Criteria**

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<b>Criterion</b>	<b>Definition</b>
Non-candidacy for acute renal replacement therapy	Decision that patient is not a candidate for renal replacement therapy made by <ol style="list-style-type: none"><li>1. Patient</li><li>2. Surrogate decision-maker; and/or</li><li>3. Clinical treatment team</li></ol>
Moribund state	Patient not expected to survive more than 24 hours
Patient not expected to survive 28-days because of an irreversible chronic medical condition	Underlying terminal chronic medical condition (e.g., end-stage malignancy)
Comfort-measures only status	Goal of therapy limited to palliation with death inevitable
Participation in a concurrent interventional study	Participation in a concurrent interventional study. Patients who are participating in observational studies are not excluded
Patient/surrogate refusal	Refusal to participate by: <ol style="list-style-type: none"><li>1. Patient, if patient retains decision-making capacity; or</li><li>2. Surrogate decision-maker if patient lacks decision-making capacity</li></ol>
Physician refusal	Clinical treating team does not consent to have patient participate in study

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**Table 4****Clinical Criteria for Diagnosis of Etiologies of ARF other than ATN**

<b>Etiology of ARF</b>	<b>Clinical Criteria to Suggest Diagnosis</b>
Pre-renal azotemia	Primary: <ol style="list-style-type: none"><li>1. Underlying absolute or effective (in setting of CHF or cirrhosis) hypovolemia, and</li><li>2. Improvement in renal function with volume loading or inotropic support</li></ol> Secondary (suggestive but not diagnostic): <ol style="list-style-type: none"><li>1. Fractional excretion of sodium &lt; 1% and/or fractional excretion of urea &lt;35%;</li><li>2. Bland urine sediment</li></ol>
Obstructive uropathy	<ol style="list-style-type: none"><li>1. Bladder outlet obstruction diagnosed by elevated post-void residual bladder function;</li><li>2. New or progressive hydronephrosis on renal ultrasound or other imaging; or</li><li>3. Improvement in renal function following decompression of urinary collecting system</li></ol>
Allergic interstitial nephritis	<ol style="list-style-type: none"><li>1. Appropriate clinical setting (e.g., drug exposure, infection);</li><li>2. Clinical syndrome of fever and/or skin rash and/or eosinophilia;</li><li>3. Urine sediment with hematuria, pyuria, or leukocyte casts; and</li><li>4. Eosinophiluria (the negative predictive value of eosinophiluria is approximately 90%, however the positive predictive value is only ~50%)</li></ol>
Acute or rapidly progressive glomerulonephritis	<ol style="list-style-type: none"><li>1. Appropriate clinical setting (e.g., recent Strep infection, endocarditis, etc...);</li><li>2. Positive serologic markers (e.g., low serum complement levels, positive anti-GBM antibodies, or positive ANCA);</li><li>3. Urine sediment with dysmorphic red blood cells or red blood cell casts; and/or</li><li>4. Renal biopsy demonstrating proliferative or crescentic glomerulonephritis</li></ol>
Vasculitis	<ol style="list-style-type: none"><li>1. Appropriate clinical setting (e.g., multisystem disease)</li><li>2. Positive serologic marker(s) (e.g., low serum complement levels, positive ANA, positive serum cryoglobulins, positive hepatitis B or hepatitis C serologies)</li><li>3. Urine sediment with dysmorphic red blood cells or red blood cell casts; and/or</li><li>4. Biopsy of kidney or other tissue with acute vasculitis</li></ol>

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**Clinical Criteria for Diagnosis of Etiologies of ARF other than ATN**

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<b>Etiology of ARF</b>	<b>Clinical Criteria to Suggest Diagnosis</b>
Hemolytic-uremic syndrome (HUS)/Thrombotic thrombocytopenic purpura (TTP)	<ol style="list-style-type: none"> <li>1. Microangiopathic hemolytic anemia (with schistocytes on peripheral blood smear and elevated LDH);</li> <li>2. Thrombocytopenia;</li> <li>3. Absence of disseminated intravascular coagulation (DIC)</li> </ol>
Malignant hypertension	<ol style="list-style-type: none"> <li>1. Severe (Stage III) hypertension;</li> <li>2. Neurologic changes;</li> <li>3. Retinal hemorrhages, exudates or papilledema; and</li> <li>4. Hematuria and/or red blood cell casts</li> </ol>
Scleroderma renal crisis	<ol style="list-style-type: none"> <li>1. Diagnosis of scleroderma;</li> <li>2. Acute onset of renal failure; and</li> <li>3. Abrupt onset of moderate to severe hypertension</li> </ol>
Atheroembolism	<ol style="list-style-type: none"> <li>1. Clinical setting (e.g., recent intra-arterial catheterization, recent vascular surgery or anticoagulation);</li> <li>2. Presence of some or all of the following: <ul style="list-style-type: none"> <li>- cutaneous manifestations (e.g., livedo reticularis, digital ischemia);</li> <li>- extra-renal visceral involvement;</li> <li>- atheroemboli visible on retinal exam (Hollenhorst plaques);</li> <li>- eosinophilia;</li> <li>- eosinophiluria;</li> <li>- hypocomplementemia; or</li> <li>- cutaneous or other biopsy positive for atheroemboli</li> </ul> </li> </ol>
Multiple myeloma	<ol style="list-style-type: none"> <li>1. Known or suspected diagnosis of multiple myeloma</li> <li>2. Presence of immunoglobulin light chains in the urine on UPEP</li> <li>3. Serum paraprotein detected on SPEP</li> </ol>

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**Clinical Criteria for Diagnosis of Etiologies of ARF other than ATN**

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**Etiology of ARF**

**Clinical Criteria to Suggest Diagnosis**

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Functional or surgical nephrectomy

1. Surgical nephrectomy (bilateral); or
2. Bilateral renal infarction (secondary to thromboemboli, renal artery dissection or renal vein thrombosis) manifested by:
  - clinical presentation with flank pain, hematuria and/or elevated LDH
  - renal imaging by angiography, CT scan or MRI

Hepatorenal syndrome

- Major criteria:
1. Chronic or acute liver disease with advanced hepatic failure and portal hypertension;
  2. Absence of shock, ongoing bacterial infection, fluid loss and current or recent treatment with nephrotoxic drugs
  3. Absence of ongoing GI fluid losses or renal fluid losses
  4. Absence of sustained improvement in renal function after withdrawal of diuretics and expansion of plasma volume with 1.5 L of isotonic saline (administered over 4 to 6 hours); and
  5. Absence of proteinuria > 500 mg/d, absence of ultrasound evidence of obstructive uropathy or parenchymal renal disease

Minor criteria

1. Urine volume < 500 mL/d;
2. Urine sodium < 10 mEq/L;
3. Urine osmolality > plasma osmolality;
4. Urine red blood cells < 50 per high-powered field;
5. Serum sodium concentration < 130 mEq/L

Cyclosporin or tacrolimus nephrotoxicity

Elevated cyclosporin or tacrolimus drug levels as compared to prior baseline levels; and Improvement in renal function following reduction in drug dose or discontinuation of drug.

Tumor Lysis Syndrome

1. Rapidly growing malignancy;
  2. Serum uric acid > 20mg/dL;
- Urine uric acid to creatinine ratio > 1.

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## **VI. THE INFORMED CONSENT PROCESS**

### **A. The Informed Consent Procedure**

Informed consent will be obtained from all patients (or their legally authorized representative if they lack decision-making capacity, referred to as the surrogate decision-maker) prior to participation in this study. In order to provide informed consent, the patient (or the surrogate decision-maker) must understand the details of the study and agree, without coercion, to participation in the study. Merely obtaining a signature on a consent form does not constitute informed consent. Rather, signing of the consent form provides one form of documentation of the consent process.

In order to obtain informed consent, you must completely explain the study to the patient or the surrogate decision-maker, providing a copy of the detailed consent form along with any supplementary material about the study to read and review. The written consent form must address all of the following items:

1. The name of the study
2. The name of the Principal Investigator
3. An explanation that the study involves research
4. An explanation that the purpose of the study is to determine whether a strategy of more intensive renal replacement therapy (dialysis) in patients with acute kidney failure results in increased survival as compared to the conventional management of renal replacement therapy in acute kidney failure.
5. An explanation that the active treatment portion of the study will last up to 4 weeks and that additional follow-up by telephone or mail will occur over a period of one year.

6. A description of the two treatment strategies.
7. A description of randomization.
8. A description that participation in the study may require additional dialysis treatments over usual therapy.
9. A description that participation in the study will require additional blood tests.
10. A description that the patient's Social Security number will be used to identify records of medical care and to track the patient's survival after hospital discharge.
11. A description that the alternative to participation in this study will be to receive renal replacement therapy (dialysis) not as part of the study.
12. A description that all records will be kept confidential, but that records may be examined by representatives of the VA, the National Institutes of Health, and/or the FDA.
13. An explanation of whom to contact for answers to questions about the research and about research subjects' rights.
14. An explanation of whom to contact in the event of research-related injury.
15. A statement that participation in the study is voluntary and that a decision not to participate or to withdraw from the study after initially agreeing to participate will involve no penalty, loss of benefits or reduction in access to medical care.
16. A statement that there will be no cost for the treatments provided as part of this study.
17. A statement that there will be no payment for participation in this study.

The use of a standardized consent form aids in assuring that subjects/surrogate decision-makers receive adequate and consistent information about the trial, but does not supplant the

need to have a one-on-one discussion with the patient/surrogate decision-maker. In your discussion you should review the following key issues:

1. The study represents research;
2. The general intent of the study;
3. The two strategies for renal support that will be utilized;
4. The random assignment of patients to the two treatment strategies;
5. The risks associated with the study;
6. The use of personal identifiers, including the use of the patient's Social Security number as a unique patient identifier, emphasizing that all personal identifying information will be kept in a data-file separate from the files containing other study data.

After describing the study to the patient/surrogate decision-maker and ensuring that they have had an opportunity to carefully read the consent form and any supplementary materials, you should ensure that any questions about the study have been answered. In addition, the patient/surrogate decision-maker must have an opportunity to review and discuss the study with the investigator (or an approved designee) and have any additional questions about the study answered.

If after being fully informed about the study, the patient/surrogate decision-maker agrees to participate in the study, they need to provide a witnessed signature (dated and timed) on the consent form. The consent form must also be signed by the person actually obtaining informed consent as well as by the investigator. You must also document the informed consent process in a detailed progress note in the medical record.

At VA sites you need to place the original completed and signed consent document in the patient's study file and place a copy of it in the patient's medical record. At non-VA sites, you need to place the original of the completed consent document, or a copy of it, in the patient's study file and patient's medical record, in accordance with current local site policy. In addition, you need to provide a copy of the signed consent document to the patient/surrogate decision-maker. If required by local policy, you will also provide a copy to your Research Office/IRB. You must also send a copy of the completed consent form to the West Haven CSPCC.

## **B. Surrogate Consent**

The patients eligible for this trial will be critically ill and the majority will be incapable of providing informed consent due to acute delirium or pharmacologic sedation. For this reason, we anticipate that surrogate consent from the patient's legally authorized representative will be required for the majority of patients. The ability to utilize surrogate consent must be explicitly approved by your IRB and documented in the IRB minutes or approval memorandum maintained in your regulatory file and provided to the West Haven CSPCC.

In order to obtain surrogate consent, two physicians must determine and document in the medical record that the patient lacks decision-making capacity and that there is little or no likelihood that the patient will regain decision-making capacity within the time frame required for enrollment in this study. At least one of the physicians should not be a study investigator. In the majority of patients, we anticipate little difficulty in assessing whether or not the patient has decision-making capacity. The primary criterion for this assessment will be the ability of the patient to comprehend the design, risks and benefits of participation in this study. If there is uncertainty regarding the patient's decision-making capacity, documentation of mental status

using an objective tool such as the Mini Mental Status Examination or the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) should be utilized. Copies of these two assessments can be found at the end of this section.

At VA sites, the surrogate decision-maker will be identified based on the following order of priority unless otherwise specified by applicable state law:

1. Court-appointed guardian
2. Health care agent designated by a Durable Power of Attorney for Health Care (DPAHC) or similar document
3. Spouse
4. Adult child (18 years of age or older)
5. Parent
6. Adult sibling (18 years of age or older)
7. Grandparent
8. Adult grandchild (18 years of age or older)

If no such individual can be identified, the Chief-of-Staff and hospital counsel should be contacted. At non-VA sites, identification of the patient's legally authorized representative for surrogate consent must be in accordance with prevailing state law.

The actual consent process when surrogate consent is used needs to be the same as if the patient were providing consent for himself/herself. The surrogate decision-maker needs to be instructed, however, that they need to decide whether or not to consent to have the patient participate based on what they thought the patient would do if the patient were making the decision (i.e., substituted judgment). In addition, you need to inform the surrogate decision-

maker that the patient will be asked to re-consent to participation in the study if and when they regain decision-making capacity.

### **C. Faxed Documentation of Signature Consent**

The use of faxed documentation of signature for informed consent is permitted in this study but may only be used if approved by the local IRB of jurisdiction. All requirements for obtaining informed consent, as specified in the Common Rule (38CFR16.116 through 38CFR16.117, and 45CFR46.116 through 45CFR46.117), VHA Handbook 1200.5, Appendix C, and Section XIII of the ATN Study Protocol, apply to informed consent using faxed documentation of signature for informed consent.

In particular, all the requirements for the use of surrogate consent as delineated above must be fulfilled, including: When surrogate informed consent is obtained by telephone with faxed documentation of signature, a copy of the informed consent document is to be sent to the subject's legally authorized representative by facsimile. Following confirmation that the informed consent document has been received by the subject's legally authorized representative, the consent interview will be conducted by telephone between a member of the study team authorized to obtain informed consent and the subject's legally authorized representative, allowing the subject's legally authorized representative to read the consent document as it is discussed. If the subject's legally authorized representative agrees to the subject's participation in the study, he/she will then sign and date the informed consent document on the signature line for subject's representative followed by a witness signing and dating the informed consent document on the witness signature line. The signed informed consent document will then be returned to the investigator by facsimile.

At a minimum, the procedure for the use of faxed documentation of signature informed consent shall include all of the following:

1. A copy of the IRB approved informed consent form shall be provided to the subject's legally authorized representative (surrogate decision-maker) prior to the consent interview.
2. In the consent interview, the investigator (or his/her approved designee) shall review all of the information specified in Section XIII. A. of the ATN Study protocol to the surrogate decision-maker, ensuring that he/she is fully informed of the risks and benefits associated with participation in the ATN Study.
3. The investigator (or his/her approved designee) shall inform the surrogate decision-maker that his/her obligation is to provide substituted judgment for the patient, based on his/her determination of what the subject would have done if able to express an opinion. If the surrogate decision-maker does not know what the patient would have decided, he/she shall be instructed to provide or refuse consent on the basis of his/her judgment of what is in the patient's best interest.
4. The surrogate decision-maker shall be afforded ample opportunity to read the entire IRB approved informed consent document and to have the site investigator (or his/her approved designee) answer all questions regarding the study prior to deciding whether or not to provide consent.
5. If the surrogate decision-maker agrees to provide consent for participation in the ATN Study, he/she shall be instructed to execute the informed consent form, initialing, signing and dating the form, where appropriate. The surrogate decision-

maker's signature must be witnessed and the witness must sign and date the informed consent form.

6. The surrogate decision-maker shall be instructed to fax the executed informed consent form to the study site. The subject may not be enrolled and randomized into the study until the faxed executed informed consent form is received by the study site.
7. The investigator (or his/her approved designee) shall sign and date the faxed executed copy of the informed consent form.
8. A copy of the executed informed consent document, signed by the site investigator (or his/her approved designee) shall be returned to the surrogate decision maker.
9. The original faxed executed consent form will be filed in the subject's research file
10. The surrogate decision-maker shall be asked to return the copy of the executed informed consent form with his/her original signature to the study site by mail or in person. This copy of the consent form is to be filed in the subject's research file in addition to the original received fax of the executed consent form that was used for subject enrollment. The study site must attempt to obtain this copy of the consent form until study day 60 or patient death, whichever comes first. If the copy of the informed consent form with the surrogate decision-maker's original signature it is not returned to the study site, a note to file documenting the efforts to obtain it must be filed in the subject's study folder.
11. The entire informed consent process shall be documented in a detailed progress note in the subject's medical record.

The use of faxed documentation of signature for informed consent is not to be used merely as a matter of convenience. Its use should be limited to situations in which geographical barriers prohibit obtaining informed consent in person from the subject's legally authorized representative.

#### **D. Re-Consent**

All patients enrolled in the study based on surrogate consent must be re-consented if and when they regain decision-making capacity. The criteria for determining whether a patient has regained decision-making capacity will be the same as the criteria used to initially assess decision-making capacity.

The re-consent process should be identical to the original consent process with the exception that you will inform the patient of who provided consent for their participation in the study and will provide them with the opportunity to either consent to or refuse to consent to continued participation in the study. The signature page of the consent form for re-consent therefore differs from the original consent form in that it has a place for specifying who provided the original consent and blanks to be initialed by the patient to indicate consent or refusal of consent to continued participation in the study. You need to have the patient sign the consent form whether or not he/she agrees to continued participation in the trial. If a subject revokes consent to further participation in the study, data already collected will continue to be utilized unless specifically revoked in writing. As with the initial consent, at VA sites, you need to place the original of the signed consent form in the patient's study file and a copy in the patient's medical record. At non-VA sites, you need to place the original or a copy of the signed consent in the patient's study file and in the patient's medical record, consistent with current local site

policy. All sites must provide copies of the signed consent form to the patient, to the local IRB (if required) and to the West haven CSPCC. The re-consent process also needs to be documented in a signed and dated progress note in the patient's medical record.

If a patient has not regained decision-making capacity by day 28, you will need to contact the individual providing surrogate consent for the day 60 and/or 1-year follow-ups to determine if the patient has regained decision-making capacity. If the surrogate indicates that the patient is able to provide consent, you will need to provide a copy of the consent form to the subject for his/her review. You should discuss the study with the subject by telephone prior to sending them the consent form and arrange a second telephone call after they have had an opportunity to review the consent form (or meet in person if he/she is able and willing to come into the facility) to discuss the study and answer any questions. If the patient is unable or unwilling to sign the consent form in person, he/she may sign the consent form, having it witnessed by a family member or other individual and send the executed consent form to you by mail.

**A. Mini Mental Status Examination (MMSE)**

<b>Task</b>	<b>Instructions</b>	<b>Scoring</b>	
Date Orientation	"Tell me the date?" Ask for omitted items.	One point each for year, season, date, day of week, and month	5
Place Orientation	"Where are you?" Ask for omitted items.	One point each for state, county, town, building, and floor or room	5
Register 3 Objects	Name three objects slowly and clearly. Ask the patient to repeat them.	One point for each item correctly repeated	3
Serial Sevens	Ask the patient to count backwards from 100 by 7. Stop after five answers. (Or ask them to spell "world" backwards.)	One point for each correct answer (or letter)	5
Recall 3 Objects	Ask the patient to recall the objects mentioned above.	One point for each item correctly remembered	3
Naming	Point to your watch and ask the patient "what is this?" Repeat with a pencil.	One point for each correct answer	2
Repeating a Phrase	Ask the patient to say "no ifs, ands, or buts."	One point if successful on first try	1
Verbal Commands	Give the patient a plain piece of paper and say "Take this paper in your right hand, fold it in half, and put it on the floor."	One point for each correct action	3
Written Commands	Show the patient a piece of paper with "CLOSE YOUR EYES" printed on it.	One point if the patient's eyes close	1
Writing	Ask the patient to write a sentence.	One point if sentence has a subject, a verb, and makes sense	1
Drawing	Ask the patient to copy a pair of intersecting pentagons onto a piece of paper.	One point if the figure has ten corners and two intersecting lines	1
<b>Scoring</b>	A score of 24 or above is considered normal.		<b>30</b>

Adapted from: Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res 1975; 12:189-98.

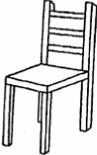
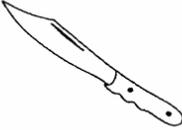
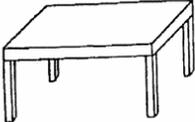
**B. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)**

Features and Descriptions	Absent	Present
<b>I. Acute onset or fluctuating course*</b>		
A. Is there evidence of an acute change in mental status from the baseline? B. Or, did the (abnormal) behavior fluctuate during the past 24 hours, that is, tend to come and go or increase and decrease in severity as evidenced by fluctuations on the Richmond Agitation Sedation Scale (RASS) or the Glasgow Coma Scale?		
<b>II. Inattention†</b>		
Did the patient have difficulty focusing attention as evidenced by a score of less than 8 correct answers on either the visual or auditory components of the Attention Screening Examination (ASE)?		
<b>III. Disorganized thinking</b>		
Is there evidence of disorganized or incoherent thinking as evidenced by incorrect answers to 3 or more of the 4 questions and inability to follow the commands? Questions 1. Will a stone float on water? 2. Are there fish in the sea? 3. Does 1 pound weigh more than 2 pounds? 4. Can you use a hammer to pound a nail? Commands 1. Are you having unclear thinking? 2. Hold up this many fingers. (Examiner holds 2 fingers in front of the patient.) 3. Now do the same thing with the other hand (without holding the 2 fingers in front of the patient). (If the patient is already extubated from the ventilator, determine whether the patient's thinking is disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject.)		
<b>IV. Altered level of consciousness</b>		
Is the patient's level of consciousness anything other than alert, such as being vigilant or lethargic or in a stupor, or coma? Alert: spontaneously fully aware of environment and interacts appropriately Vigilant: hyperalert Lethargic: drowsy but easily aroused, unaware of some elements in the environment or not spontaneously interacting with the interviewer; becomes fully aware and appropriately interactive when prodded minimally Stupor: difficult to arouse, unaware of some or all elements in the environment or not spontaneously interacting with the interviewer; becomes incompletely aware when prodded strongly; can be aroused only by vigorous and repeated stimuli and as soon as the stimulus ceases, stuporous subject lapses back into unresponsive state Coma: unarousable, unaware of all elements in the environment with no spontaneous interaction or awareness of the interviewer so that the interview is impossible even with maximal prodding		
<b>Overall CAM-ICU Assessment (Features 1 and 2 and either Feature 3 or 4): Yes___ No___</b>		

\*The scores included in the 10-point RASS range from a high of 4 (combative) to a low of -5 (deeply comatose and unresponsive). Under the RASS system, patients who were spontaneously alert, calm, and not agitated were scored at 0 (neutral zone). Anxious or agitated patients received a range of scores depending on their level of anxiety: 1 for anxious, 2 for agitated (fighting ventilator), 3 for very agitated (pulling on or removing catheters), or 4 for combative (violent and a danger to staff). The scores -1 to -5 were assigned for patients with varying degrees of sedation based on their ability to maintain eye contact: -1 for more than 10 seconds, -2 for less than 10 seconds, and -3 for eye opening but no eye contact. If physical stimulation was required, then the patients were scored as either -4 for eye opening or movement with physical or painful stimulation or -5 for no response to physical or painful stimulation. The RASS has excellent interrater reliability and intraclass correlation coefficients of 0.95 and 0.97, respectively, and has been validated against visual analog scale and geropsychiatric diagnoses in 2 ICU studies.<sup>37,38</sup>

†In completing the visual ASE, the patients were shown 5 simple pictures (previously published<sup>39</sup>) at 3-second intervals and asked to remember them. They were then immediately shown 10 subsequent pictures and asked to nod "yes" or "no" to indicate whether they had or had not just seen each of the pictures. Since 5 pictures had been shown to them already, for which the correct response was to nod "yes," and 5 others were new, for which the correct response was to shake their heads "no," patients scored perfectly if they achieved 10 correct responses. Scoring accounted for either errors of omission (indicating "no" for a previously shown picture) or for errors of commission (indicating "yes" for a picture not previously shown). In completing the auditory ASE, patients were asked to squeeze the rater's hand whenever they heard the letter A during the recitation of a series of 10 letters. The rater then read 10 letters from the following list in a normal tone at a rate of 1 letter per second: S, A, H, E, V, A, A, R, A, T. A scoring method similar to that of the visual ASE was used for the auditory ASE testing.

This table may be reproduced without permission for clinical use only (Ely EW et al. *JAMA*. 2001;286:2707-2710).

<p>The Attention Screening Examination for the ICU – Picture Recognition ASE</p> <ul style="list-style-type: none"> <li>This is a test of attention, the ability of the patient to concentrate and demonstrate short term memory.</li> <li>This test, created by Hart and colleagues, was found to be a reliable and valid instrument for detecting delirium among mechanically ventilated patients.</li> </ul> <p><small>Hart et al. Psychosomatics 1996; 37:533-546 Hart et al. J Psychosom Res 1997; 43:417-423</small></p>	<p><b>1st Step: 5 pictures</b></p> <ul style="list-style-type: none"> <li>Say to the patient: "Mr or Mrs. <u>   X   </u>, I am going to show you pictures of some common objects. Watch carefully and try to remember each picture because I will ask what pictures you have seen."</li> <li>Then show Step 1 of Form A or Form B.</li> <li>Alternate daily between Form 1 and Form 2.</li> </ul>		
<p><b>2nd Step: 10 pictures</b></p> <ul style="list-style-type: none"> <li>Say to the patient: "Now I am going to show you some more pictures. Some of these you have already seen and some are new. Let me know whether or not you saw the picture before by nodding your head 'yes' (demonstrate) or 'no' (demonstrate)."</li> <li>Then show Step 2 of Form A or Form B, whichever form was used in Step 1.</li> </ul>	<p><b>Scoring the ASE</b></p> <ul style="list-style-type: none"> <li>This test is scored by the number of correct "yes" or "no" answers out of a possible 10 during the second step using Forms A or B.</li> <li>The pictures are listed in the following slides. In the ICU, they are shown on large, laminated, buff colored paper for ease of viewing by the elderly or visually impaired.</li> </ul>		
			
			
			
			

Form A (step 1)

Key  
Cup  
Car  
Table  
Hammer

Form A (step 2)

Key  
Cup  
Car  
Table  
Hammer  
Glass  
Lock  
Truck  
Chair  
Saw

Form B (step 1)

Boot  
Dog  
Knife  
Pants  
Paint brush

Form B (step 1)

Boot  
Dog  
Knife  
Pants  
Paint brush  
Fork  
Cat  
Dress  
Toothbrush  
Shoe

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## **VII. PATIENT RANDOMIZATION**

If the patient fulfills all the inclusion criteria, is not excluded by any of the exclusion criteria on the screening form (Form 01), fits in the enrollment window, and you have obtained signed informed consent from the patient or from the patient's surrogate, you are ready to randomize the patient. You must be absolutely sure that the patient fulfills all the inclusion criteria and does not fulfill any of the exclusion criteria before having the patient randomized by the interactive touch-tone randomization system (ITTRS). If you make a mistake and randomize a patient who is not eligible, this will be considered a protocol violation.

The next step is to complete the randomization form (Form 03) through part E. Since the randomization is stratified by cardiovascular SOFA score and by Oliguric status, please make sure you fill in the correct cardiovascular SOFA score and Oliguric status on Form 03. To randomize the patient and obtain the treatment assignment, you will use the interactive touch-tone randomization system (ITTRS – see the directions given below). You may randomize a patient using this system at any time of day, seven days a week. In the event that the ITTRS is down, please call Christine Dalzell at Perry Point CSPCC, (410) 642-2411 x5313, Monday through Friday, between the hours of 7 a.m. and 5 p.m. EST.

After receiving the treatment assignment from the ITTRS, complete Form 03 and FAX it, along with the screening form and the signed informed consent, as soon as possible to Vanessa McBride at the West Haven CSPCC (203-937-3858).

### **A. How To Use The ITTRS**

If you feel unsure about using the ITTRS, you may first practice with a test call before calling to do the actual randomization. The phone number to use when making a test call is the

same as the number you would use when making a call for an actual randomization – (410) 642-1175. When making a test call, use study number 530 and study password 830. The site number to use for the test call is 103 and the site password for the test call is 103. **Do not use your actual site number for a test call.**

In order for you to use the ITTRS, you will be assigned two passwords by the Perry Point CSPCC. The passwords are needed to ensure that only authorized personnel are randomizing patients. If the passwords do not match the study or site number, you will not be able to randomize the patient. Be sure to have Form 03 (Randomization Form) in front of you with all information filled out up to, but not including, the treatment assignment (Item F), to ensure that you enter the correct patient information into the ITTRS.

Each time you call the ITTRS to randomize a patient, you will need the following:

- Study number (530) and study password
- 3-digit site code and password
- Site personnel ID number and 2 initials
- 3-digit subject number for the patient that you are randomizing
- 2 or 3-character initials for the patient that you are randomizing
- SOFA score and oliguric status for the patient that you are randomizing

In addition to the above-listed information, you will also be asked to verify the patient's eligibility for the study and that informed consent document has been obtained, i.e., that the informed consent form has been signed by the patient or by the patient's surrogate if the patient lacks decision-making capacity.

A sample of the ITTRS randomization process is provided beginning on page 5 of this section. The patient initials will be entered using the letter conversion codes as shown on page 7 of this section. If the patient has only 2 initials, enter them as described on page 7 and then press the pound sign twice (##).

**What to do if your patient has been randomized in error:** If, after you have gone through the entire phone randomization procedure and have received a treatment assignment for the patient, you discover that you have entered an incorrect Cardiovascular SOFA Score or the wrong value for Oliguria, and your patient has not been started on the randomized treatment modality, you may call Christine Dalzell at Perry Point [(410)-642-2411, x5313] and have her remove that patient from the randomization file. Do not randomize any other patients in the meantime until Ms. Dalzell has removed the incorrectly randomized patient from the randomization file.

Once a patient has been successfully randomized through the ITTRS you must complete the remainder of the randomization form (Form 03) by filling in the treatment assignment that you were given by the ITTRS and then you must FAX Form 01 (Screening Form), the signed informed consent with the cover sheet (Form 2T), and the completed randomization form (Form 03) to Vanessa McBride at the West Haven CSPCC. The Fax number is (203) 937-3858. A letter generated by the ITTRS confirming the randomization, with a schedule giving the 28-day, 60-day, and 12-month follow-up dates, will be automatically faxed to your site. The originals of the data forms for this patient and a copy of the signed informed consent must be FEDEXed to the West Haven CSPCC in a timely manner as described in Section IX of this manual.

If you have any questions about the randomization process, or have problems accessing the ITTRS, please contact the Perry Point CSPCC at (410) 642-2411, x5313.

Perry Point Cooperative Studies  
Interactive Touch-Tone Randomization System (ITTRS)  
(410) 642-1175

Randomizing a Patient

- ITTRS: Welcome to Perry Point Cooperative Studies Randomization System.
- ITTRS: Please enter your Study Number followed by the pound sign.  
Caller: Enter on telephone keypad 530#
- ITTRS: Please enter the three-digit study password.  
Caller: Enter on the telephone keypad 123
- ITTRS: Please enter your site number followed by the pound sign.  
Caller: Enter on the telephone keypad 689#
- ITTRS: Please enter your site password.  
Caller: Enter on the telephone keypad 000
- ITTRS: Please enter the two-digit site personnel's ID number.  
Caller: Enter on the telephone keypad 02
- ITTRS: The site personnel ID number you entered was 02. If this is correct press 1, if this is incorrect press 2, to hear your response again press 3.  
Caller: Enter on the telephone keypad 1 or 2 or 3
- ITTRS: Please enter the site personnel's initials. (Note: Only 2 initials are allowed.)  
Caller: Enter on the telephone keypad 71 41 (ex:PG)
- ITTRS: The initials you entered were PG. If this is correct press 1, if this is incorrect press 2, to hear your response again press 3.  
Caller: Enter on the telephone keypad 1 or 2 or 3
- ITTRS: Please enter this subject's 3 digit ID number  
Caller: Enter on the telephone keypad 185
- ITTRS: The subject ID number you entered was 185. If this is correct press 1, if this is incorrect press 2, to hear your response again press 3.  
Caller: Enter on the telephone keypad 1 or 2 or 3
- ITTRS: Please enter this subject's 3 character initials. If the subject has only two initials, please enter the initials and then press the pound sign (#) twice.  
Caller: Enter on the telephone keypad 41 73 82 (ex:GRU)
- ITTRS: The initials you entered were GRU. If this is correct press 1, if this is

incorrect press 2, to hear your response again press 3.

**Caller:** Enter on the telephone keypad 1 or 2 or 3

**ITTRS:** If the patient has met all eligibility criteria, press 1, if not press 2.

**Caller:** Enter on the telephone keypad 1 or 2

**ITTRS:** If the patient, or the patient's surrogate has signed the study consent form press 1, if not press 2.

**Caller:** Enter on the telephone keypad 1 or 2

**ITTRS:** Please enter this subject's cardiovascular organ failure score.

**Caller:** Enter on the telephone keypad 0, 1, 2, 3, or 4

**ITTRS:** The cardiovascular organ failure score you entered was 3. If this is correct press 1, if this is incorrect press 2, to hear your response again press 3.

**Caller:** Enter on the telephone keypad 1 or 2 or 3

**ITTRS:** Is the patient oliguric? If yes, press 1, if no, press 2.

**Caller:** Enter on the telephone keypad 1 or 2

**ITTRS:** We will now review the randomization information. You are calling from center number 000. You are randomizing patient number 185. The subject's initials are GRU. This patient has a cardiovascular organ failure score of 3. The patient is not oliguric. If this information is correct, press 1. If this is incorrect, press 2, and you will be able to correct the randomization information. To hear your response again, press 3.

**Caller:** Enter on the telephone keypad 1 or 2 or 3

**ITTRS:** Please hold while the randomization information is being processed.

**ITTRS:** Patient number 185 has been randomized into study 530. The randomization date for this patient is July 1, 2003. The treatment code assigned is conventional treatment.

**ITTRS:** For verification purposes, please enter the treatment code assigned. If the treatment assignment was conventional treatment, press 1. If the treatment assignment was intensive treatment, press 2.

**Caller:** Enter on the telephone keypad 1 or 2

**ITTRS:** To repeat the randomization information, press 1, to randomize another patient, press 2, to end this call, press 9. If you need additional assistance with this randomization, please call (410) 642-2411, extension 5313.

### Letter Conversion for Reference Code

1	ABC 2	DEF 3					
			<b>A</b>	<b>21</b>		<b>P</b>	<b>71</b>
			<b>B</b>	<b>22</b>		<b>Q</b>	<b>72</b>
			<b>C</b>	<b>23</b>		<b>R</b>	<b>73</b>
						<b>S</b>	<b>74</b>
GHI 4	JKL 5	MNO 6					
			<b>D</b>	<b>31</b>		<b>T</b>	<b>81</b>
			<b>E</b>	<b>32</b>		<b>U</b>	<b>82</b>
			<b>F</b>	<b>33</b>		<b>V</b>	<b>83</b>
PQRS 7	TUV 8	WXYZ 9					
			<b>G</b>	<b>41</b>		<b>W</b>	<b>91</b>
			<b>H</b>	<b>42</b>		<b>X</b>	<b>92</b>
			<b>I</b>	<b>43</b>		<b>Y</b>	<b>93</b>
						<b>Z</b>	<b>94</b>
*	OPER 0	#	<b>J</b>	<b>51</b>			
			<b>K</b>	<b>52</b>			
			<b>L</b>	<b>53</b>			
			<b>M</b>	<b>61</b>			
			<b>N</b>	<b>62</b>			
			<b>O</b>	<b>63</b>			

To enter a letter using a telephone key-pad, it must be converted into two numbers.

First, press the key where the letter appears then press 1, 2, 3, or 4 to indicate whether the letter is the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> or 4<sup>th</sup> letter on that key.

***Example:***

**To enter a W, first press 9 because the letter W appears on that key.  
Then press 1 because W is the 1<sup>st</sup> letter on the 9 key.**

Note: If your telephone does not have letters, or does not have the letters "Q" or "Z", you must use the letter conversion chart or the telephone pad provided above. For "Q" and "Z", act as though "Q" is the second letter on the 7 key (PQRS; press 72 for "Q") and as though Z is the fourth letter on the 9 key (WXYZ; press 94 for "Z"). If the patient has only 2 initials, enter the initials and then press the pound sign (#) twice

## **VIII. PATIENT MANAGEMENT ON PROTOCOL**

### **A. Timing of Initiation of Study Therapy**

Study therapy is to be initiated within 24 hours of randomization. If, however, this would necessitate initiation of intermittent hemodialysis or SLED on a Sunday, initiation of study therapy may be deferred until the following Monday morning, if not medically contraindicated.

If renal replacement therapy was initiated prior to study enrollment and the initial treatment was IHD or SLED (no more than 1 treatment), study therapy is to be initiated:

- On the day following the initial treatment, if randomized to the intensive management arm (excluding Sunday for IHD and SLED, if medically appropriate); or
- Within two days of the initial treatment if randomized to the conventional management arm.

If renal replacement therapy was initiated prior to study enrollment and the initial treatment was CRRT (no more than 24 hours of therapy), study therapy is to be initiated within 24 hours of the start of non-protocol treatment.

### **B. General Management of Renal Replacement Therapy**

In order to ensure uniformity of treatment among sites and between patient groups it is critical that specific protocols for the performance of hemodialysis, sustained-low efficiency dialysis (SLED) and continuous venovenous hemodiafiltration (CVVHDF) be strictly adhered to.

#### ***Selection of Modality (Figure VIII-1)***

The selection of the initial modality of therapy and all subsequent changes in modality of therapy are to be based on the patient's hemodynamic status. At initiation of therapy, patients whose SOFA cardiovascular organ system score is 0-2 should be treated using intermittent hemodialysis while patients whose SOFA cardiovascular organ system score is 3-4 (hypotension

requiring the use of dopamine  $> 5$  mcg/kg/min or any dose of norepinephrine, epinephrine, phenylephrine or vasopressin to maintain a MAP  $\geq 70$  mmHg) should be treated with CVVHDF or SLED, based on usual site-specific practice. The specific modality used will be based on the available modality at each study site.

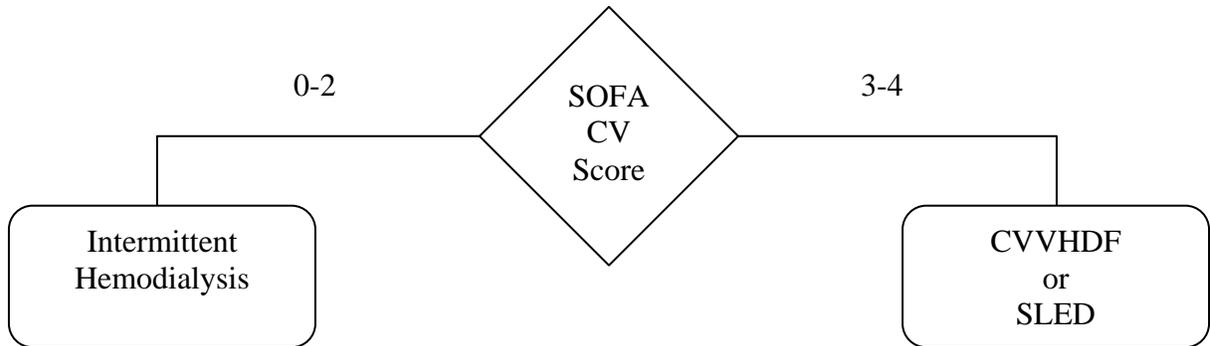
Patients who have been treated with intermittent hemodialysis should be converted to CVVHDF or SLED if their SOFA cardiovascular organ system score has increased to 3-4 at the time of the next scheduled hemodialysis treatment. Similarly, patients who have been treated with CVVHDF or SLED should convert to intermittent hemodialysis if hypotension has resolved, manifest by a SOFA cardiovascular organ system score of 0-1 for 24 hours. Patients who are randomized to intensive therapy should begin intermittent hemodialysis within 24 hours of coming off of CVVHDF, while patients on conventional therapy should convert to intermittent hemodialysis within 48 hours of coming off of continuous therapy.

For patients who are on intermittent hemodialysis, the decision regarding modality of therapy (continuation of IHD or conversion to CVVHDF/SLED) should be based on the cardiovascular SOFA score at the time of the scheduled hemodialysis treatment. For patients on CVVHDF or SLED, the decision regarding modality of therapy (continuation of CVVHDF/SLED or conversion to IHD) should be made as early as possible in the morning (e.g., 8 AM) and be based on highest of the cardiovascular SOFA scores calculated from the preceding day and the current day.

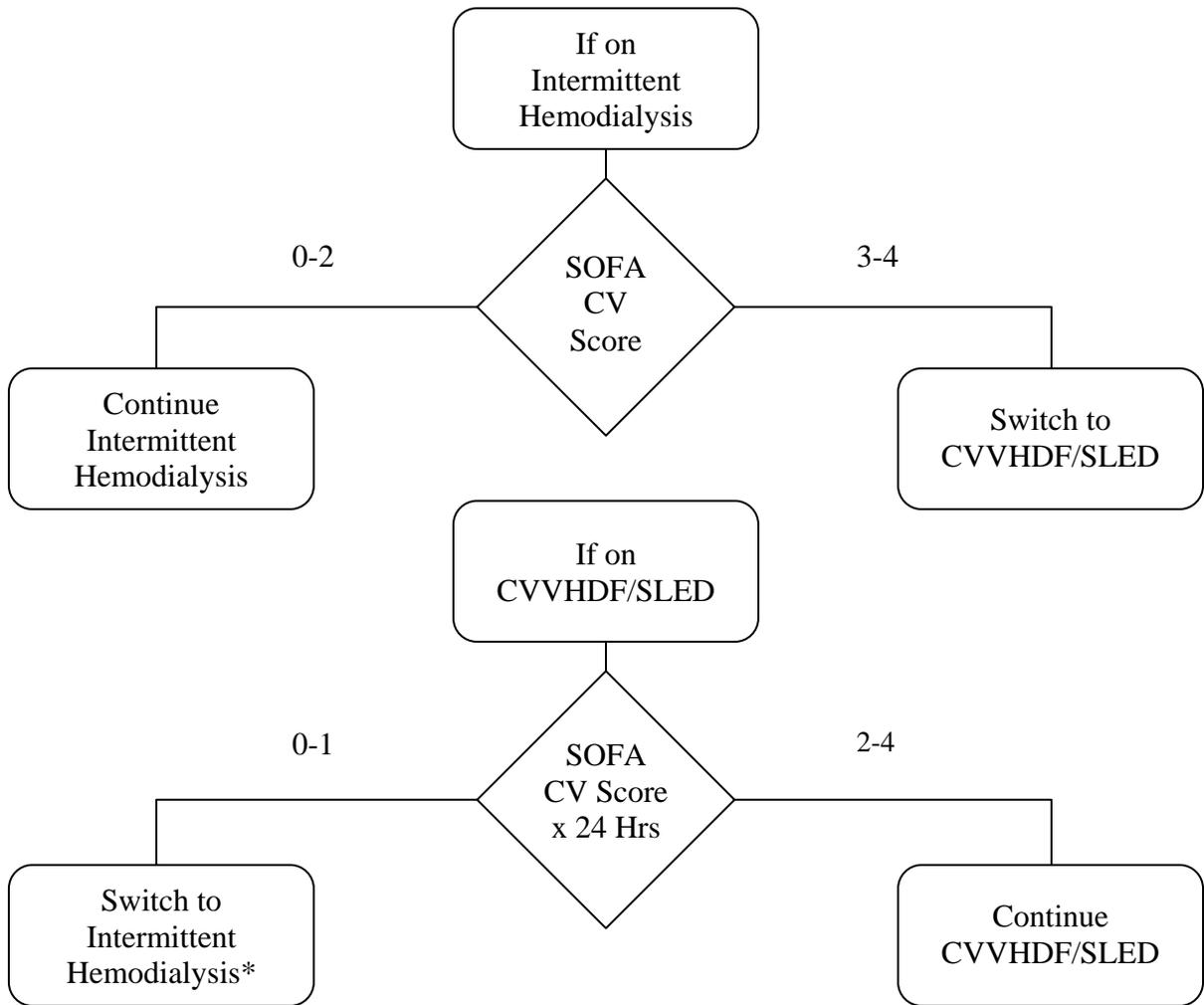
While adhering to these guidelines is the goal of patient management on protocol, it is recognized that situations will arise where these guidelines will conflict with the clinical judgment of the patient's treating physician as to the safest modality of therapy for the individual patient. Deviation from these specific guidelines may be considered on a case-by case basis in

**Figure VIII-1  
Modality of Therapy**

*Initiation of Therapy*



*Continuation of Therapy*



\* 1<sup>st</sup> Hemodialysis treatment within 24 hours if randomized to intensive therapy arm;  
1<sup>st</sup> Hemodialysis treatment within 48 hours if randomized to conventional therapy arm.

order to ensure patient safety. Such deviations DO NOT constitute protocol violations, but need to be reviewed with the Study Chairman, or his designee, within 24 hours. Efforts should be made to convert the patient to the modality of therapy designated by the protocol within 1-2 days.

Patients randomized to intensive therapy will receive intermittent hemodialysis and SLED on a 6-times per week schedule or will receive CVVHDF with an effluent flow rate of 35 mL/kg/hour. Patients randomized to the conventional therapy arm will receive intermittent hemodialysis and SLED on a 3-times per week schedule or will receive CVVHDF with an effluent flow rate of 20 mL/kg/hour.

#### **B. Management of Intermittent Hemodialysis**

General parameters for the prescription of intermittent hemodialysis are summarized in **Table VIII-1**. Hemodialysis will be provided using ultrafiltration-controlled dialysis machines and biocompatible synthetic hollow-fiber dialysis membranes (e.g., polysulfone, polyamide, polymethylmethacrylate, or polyacrylonitrile). Bicarbonate-buffered dialysate will be used for all treatments. Electrolyte composition of the dialysate and ultrafiltration goals will be prescribed by the treating physicians based on assessment of the patients' status and are not dictated by the study protocol.

**Table VIII-1  
Management of Hemodialysis**

	<i>Conventional Therapy Arm</i>	<i>Intensive Therapy Arm</i>
Treatment Schedule:	3x/week	6x/week
<b><i>Conventional and Intensive Therapy Arms</i></b>		
Hemodialyzer:	Synthetic hollow-fiber membranes	
Blood Flow Rate:	300 – 500 mL/min, prescribed by primary treating team	
Dialysate Flow Rate:	500 – 800 mL/min, prescribed by primary treating team	
Dialysate:	Bicarbonate buffered; electrolyte composition prescribed by primary treating team	
Ultrafiltration:	Prescribed by primary treating team	
Anticoagulation:	Prescribed by primary treating team	
Treatment duration:	As needed to deliver target spKt/V (usual range: 3-5 hours,)	
Initial Prescribed spKt/V:	1.4	
Target Delivered spKt/V	1.2-1.4 per treatment, monitored 3x/week for the first 2 weeks and at least weekly thereafter	

***Initial Prescribed Dose of Therapy***

Dialysis will be prescribed based on a target spKt/V of 1.4 per treatment in order to achieve a delivered dose of dialysis of 1.2 per treatment.  $Kt/V_{urea}$  is a unitless index of dialysis dose and is equal to the product of the dialyzer urea clearance ( $K$ ; mL/min) and the treatment duration ( $t$ ; min) divided by the volume of distribution of urea ( $V_{urea}$ ; mL). In order to determine the initial prescription, the product  $Kt$  will be calculated as the product  $1.4 \times V$ . The volume of distribution of urea will be calculated as described below. The treatment duration ( $t$ ) will be determined based on the urea clearance of the selected dialyzer (Coding Appendix; Section XIII, Part G) at the blood-flow prescribed as detailed in Worksheet VIII-1.

### *Calculation of $V_{urea}$*

There is no reliable formula for estimation of the volume of distribution of urea in acute renal failure. For the purpose of the study, we will estimate V as 55% of adjusted pre-morbid body weight plus edema weight, where all acute increases in body weight are assumed to be due to an increase in total body water (Worksheet VIII-2). In patients who are obese (> 30% above ideal body weight), V will be calculated based on adjusted body weight (Worksheet VIII-3), calculated as ideal body weight (Worksheet VIII-4) plus 25% of the difference between ideal and actual pre-morbid weight.

### *Monitoring of Dose of Therapy*

The delivered dose of dialysis will be monitored based on blood-side urea kinetics three-times per week for the first two weeks and at least weekly thereafter as shown in **Table VIII-2**. In order to perform kinetic modeling, blood samples for blood urea nitrogen (BUN) will be obtained immediately pre- dialysis and post-dialysis. The post-dialysis BUN sample will be obtained using the slow-flow/stop-pump technique to prevent sample dilution with recirculated blood and to minimize the variable effects of urea rebound (**Table VIII-3**). **It is critical that these samples be obtained as specified, as errors in sampling technique will result in incorrect assessment of treatment adequacy**

The value of  $spKt/V_{urea}$  will be calculated as:

$$spKt/V = - \ln (R - 0.008 \times t) + (4 - 3.5 \times R) \times 0.55 \times UF/V_{urea}$$

where Ln is the natural logarithm; R is the post dialysis BUN ÷ pre-dialysis BUN; t is the dialysis session length in hours; UF is the ultrafiltration volume in liters; and  $V_{urea}$  is the estimated volume of distribution of urea, calculated for each treatment as based on the post-dialysis weight as described above. Worksheet VIII-5 may be used to calculate  $spKt/V_{urea}$ .

**Table VIII-2**  
**Schedule for Monitoring Adequacy of Hemodialysis**

	Conventional Therapy	Intensive Therapy
Week 1	Each treatment Study treatment 1 Study treatment 2 Study treatment 3	Every other treatment Study treatment 1 Study treatment 3 Study treatment 5
Week 2	Each treatment Study treatment 4 Study treatment 5 Study treatment 6	Every other treatment Study treatment 7 Study treatment 9 Study treatment 11
Week 3	Second treatment of week Study treatment 8	Third treatment of week Study treatment 15
Week 4	Second treatment of week Study treatment 11	Third treatment of week Study treatment 21

The target delivered dose of hemodialysis is a  $spKt/V_{urea}$  of 1.2-1.4 per treatment in both treatment arms. It is critical to the success of the study that the delivered dose of hemodialysis fall within this target range (**Figure VIII-2**). If the measured  $spKt/V_{urea}$  is  $< 1.2$ , the hemodialysis prescription must be adjusted to increase the delivered dose of hemodialysis. This may be achieved through adjustment of any of the following components of the dialysis prescription:

- a. Prolongation of treatment time
- b. Use of a dialyzer with a higher urea clearance
- c. Increase in prescribed blood flow rate

Worksheet VIII-6 may be used to assist in adjusting the dialysis prescription. After the hemodialysis treatment prescription is modified,  $spKt/V_{urea}$  must be remeasured to ensure that the target dose of 1.2 per treatment is actually achieved. If the delivered  $spKt/V_{urea}$  exceeds 1.4 per

treatment, the dialysis treatment must also be modified, reducing treatment duration or using a hemodialyzer with a lower urea clearance, in order to reduce the delivered  $spKt/V_{urea}$  to within the target range of 1.2 to 1.4.

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**Table VIII-3**  
**Post-Dialysis Blood Sampling**

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1. At the completion of hemodialysis, turn off the dialysate flow and decrease the ultrafiltration rate (UFR) to 50 mL/h, to the lowest transmembrane pressure (TMP)/UFR setting, or off. If the dialysis machine does not allow for turning off the dialysate flow, or if doing so violates unit policy, decrease the dialysate flow to its minimum setting.
2. Decrease the blood flow to 50 to 100 mL/min for 15 seconds. To prevent pump shut-off as the blood flow rate is reduced, it may be necessary to manually adjust the venous pressure limits downward.

*At this point, proceed with either the slow flow or stop pump technique:*

**Slow flow sampling technique:**

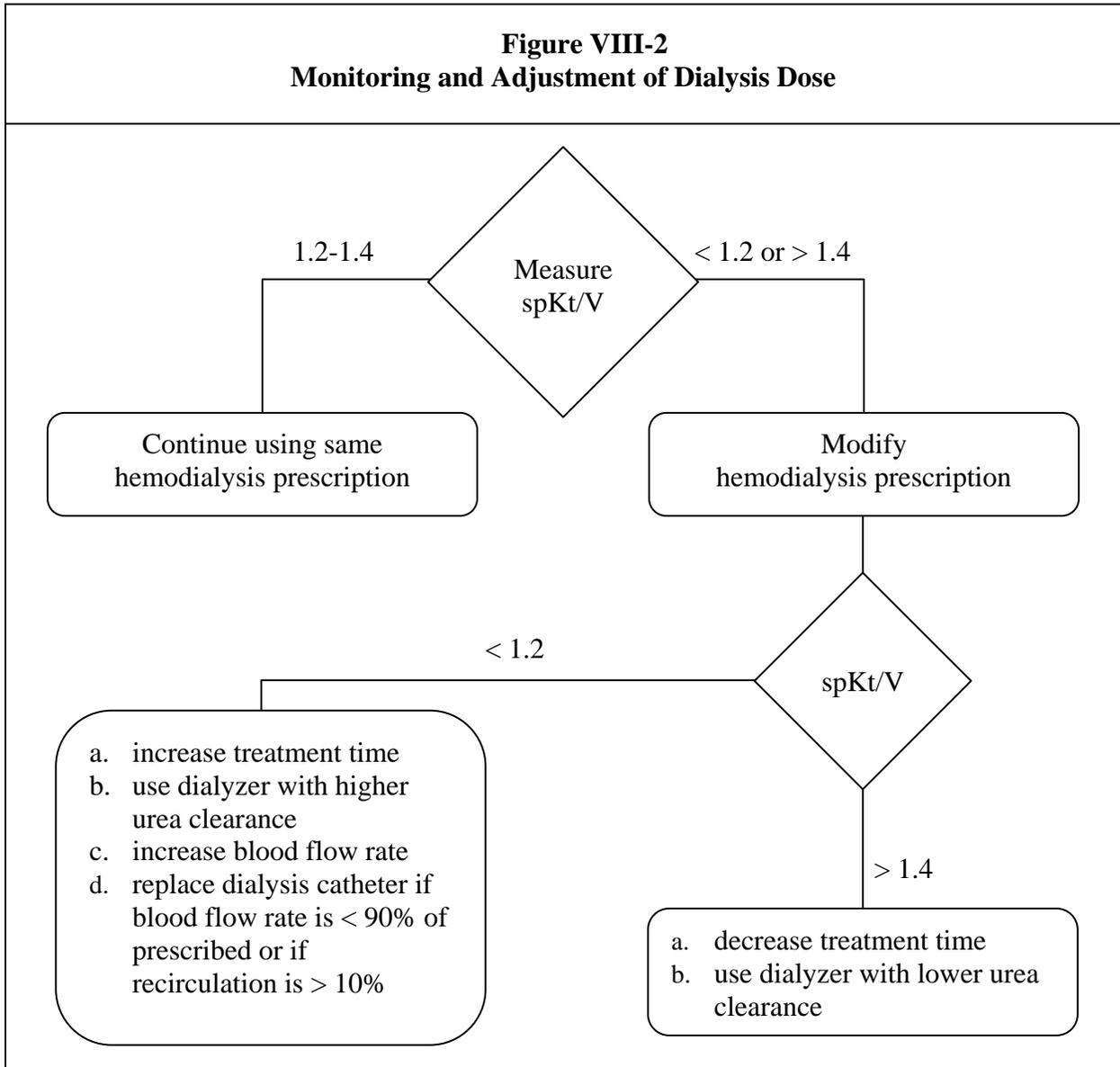
3. With the blood pump still running at 50 to 100 mL/min, draw the blood sample for postdialysis BUN measurement from the arterial sampling port closest to the patient.
4. Stop the blood pump and complete the patient disconnection procedure as per dialysis unit protocol.

**Stop pump sampling technique:**

3. Immediately stop the blood pump.
  4. Clamp the arterial and venous bloodlines. Clamp the arterial needle tubing.
  5. Blood for postdialysis BUN measurement may be sampled by needle aspiration from the arterial sampling port closest to the patient. Alternatively, blood may be obtained from the arterial needle tubing after disconnection from the arterial bloodline and attaching a Vacutainer or syringe without a needle.
  6. Blood is returned to the patient and the patient disconnection procedure proceeds as per unit protocol.
- 

In troubleshooting the reason(s) for not achieving the target delivered dose of dialysis, the two most common reasons are likely to be catheter malfunction or error in estimation of  $V_{urea}$ . Catheter malfunction may result in inability to achieve the prescribed blood flow rate. The total volume of blood processed (liters processed; blood flow rate x treatment duration) will therefore also be monitored each dialysis treatment. **If the achieved blood flow rate is less than 90% of**

the prescribed rate (liters processed less than 90% of target value), the hemodialysis catheter should be replaced. Catheter malfunction may also be manifested by increased recirculation. The catheters should also be replaced if recirculation is > 15%.



### ***Interruption of Treatment***

Interruption of hemodialysis treatment is inevitable in critically ill dialysis patients, either as the result of the patient's need to undergo emergent diagnostic or therapeutic procedures, or

because of hemodynamic instability. If an intermittent hemodialysis treatment is interrupted/discontinued prior to completion of half of the prescribed treatment time, the treatment should be resumed as soon as possible. If more than half of the prescribed treatment time has been provided, the treatment should be considered to be complete.  $Kt/V_{\text{urea}}$  should not be assessed during an interrupted treatment.

If the treatment has been prematurely terminated due to hemodynamic instability and hemodialysis cannot be resumed, the patient should be started on CVVHDF or SLED immediately, if less than half of the prescribed treatment was provided. If more than half of the prescribed treatment was provided, the decision regarding CVVHDF or SLED should be made at the time that the next hemodialysis treatment would have been provided (the next day if randomized to intensive therapy, two days subsequently if randomized to conventional therapy).

#### ***Use of Isolated Ultrafiltration***

Patients who are randomized to the conventional management arm may receive isolated ultrafiltration on non-dialysis days if required on an emergent basis for volume management. The specific indications for isolated ultrafiltration will be left to the discretion of the primary treating service, however it is expected that the use of isolated ultrafiltration will be limited to patients in whom acute volume administration or redistribution of sequestered fluid results in respiratory compromise or cardiac dysfunction manifested by objective criteria such as impaired oxygenation or right ventricular dysfunction.

### **C. Management of Continuous Renal Replacement Therapy**

General treatment parameters for the prescription of continuous renal replacement therapy (CRRT) are summarized in **Table VIII-4**. CRRT will be provided using automated equipment with integrated ultrafiltration control. All therapy will be provided as continuous

venovenous hemodiafiltration (CVVHDF) with a 1:1 ratio between dialysate and replacement fluid flow rates.

Dialysate and replacement fluids will be bicarbonate-buffered unless citrate-anticoagulation is utilized. Lactate buffered fluids (lactate concentration > 5 mmol/L) will not be utilized. The electrolyte composition of the dialysate and replacement fluids and fluid removal parameters will be prescribed by the primary treating physicians, based on changes in the patient's day to day clinical status.

**Table VIII-4  
Management of CVVHDF**

	<i>Conventional Therapy Arm</i>	<i>Intensive Therapy Arm</i>
Dialysate Flow Rate:	10 mL/kg/hr	17.5 mL/kg/hr
Replacement Fluid Flow Rate:	10 mL/kg/hr	17.5 mL/kg/hr
<b><i>Conventional and Intensive Therapy Arms</i></b>		
Treatment Schedule:	Continuous	
Hemodiafilter:	Synthetic hollow-fiber membranes	
Blood Flow Rate:	100 – 300 mL/min, prescribed by primary treating team	
Dialysate:	Bicarbonate buffered; electrolyte composition prescribed by primary treating team	
Replacement Fluid:	Bicarbonate buffered; electrolyte composition prescribed by primary treating team	
Ultrafiltration:	Prescribed by primary treating team	
Anticoagulation:	Prescribed by primary treating team	
System Change:	At least every 48 hours	

Commercially available bicarbonate-buffered fluids (Primasate®, manufactured by Gambro Renal Products, Lakewood, CO and Normocarb®, manufactured by Dialysis Solutions, Inc., Richmond Hills, ON, Canada) are FDA approved for use as dialysate. These solutions will be provided by the manufacturers at discounted prices for use in this study. These fluids are sterile, pyrogen free solutions that can be safely utilized as replacement fluids, however they are

not FDA approved for this indication. For this reason, an IND has been obtained (67,631) to permit the use of these fluids as replacement fluids for the purpose of this study. The use of these fluids will be at the discretion of the individual study sites. The compositions of these fluids are listed in **Table VIII-5**.

	Normocarb	Priskasate			
		BK0/3.5	BGK2/0	BGK 4/0	BGK 4/2.5
Sodium (mmol/L)	140	140	140	140	140
Potassium (mmol/L)	-	-	2	4	4
Bicarbonate (mmol/L)	35	32	32	32	32
Lactate (mmol/L)	-	3	3	3	3
Calcium (mmol/L)	-	1.75	-	-	1.25
Magnesium (mmol/L)	0.75	0.5	0.5	0.75	0.75
Glucose (mg/dL)	-	-	110	110	110

Dialysate and replacement fluid flow rates will be based upon pre-morbid body weight. In obese patients (> 30% above ideal body weight), calculations will be based on adjusted body weight, calculated as ideal body weight plus 25% of the difference between ideal and actual weight. Worksheet VIII-7 may be used to calculate the dialysate and replacement fluid flow rates.

Technical limitations in equipment for CVVHDF may limit the ability to maintain the 1:1 ratio between dialysate and replacement fluid in patients in the intensive therapy arm at the extreme limit of allowable body weight. In these situations, the 1:1 ratio should be maintained until the maximal replacement fluid infusion rate is attained. The additional clearance required to achieve a total clearance of 35 mL/kg/hour will be achieved by increasing the dialysate flow rate (dialysate flow will be greater than replacement fluid infusion rate). For example, In CVVHDF mode, the Gambro Prisma® machine permits a maximum replacement fluid infusion rate of 2,000 mL/hour with a maximum dialysate flow rate of 2,500 mL/hour. For a patient weighing

128.5 kg, 35 mL/kg/hour would require a total flow rate of 4,500 mL/hour. In this situation, the replacement fluid should run at 2,000 mL/hour and the dialysate should run at 2,500 mL/hour. On this machine, this deviation from the desired 1:1 ratio of dialysate to replacement fluid is only an issue for patients with an adjusted body weight in excess of 114 kg.

**In order to deliver the targeted dose of therapy, it is critical that periods of time during which the patient is off of therapy are kept as brief as possible.** We recognize that patients will need to come off of therapy for a variety of reasons, including CT and MRI scans, angiographic procedures and surgical procedures. The ICU staff needs to be educated as to the importance of resuming treatment promptly upon the patients' return to the ICU. Similarly, when systems need to be changed, either due to system clotting or routine system changes, the time off of therapy needs to be minimized, ideally, lasting no more than 60 minutes. With optimal management, actual delivered therapy should be > 85% of prescribed therapy (i.e., time off of treatment should average less than 4 hours per day). **Flow rates are not to be increased to compensate for time off of treatment**

#### **D. Management of Sustained Low-Efficiency Dialysis**

General treatment parameters for the prescription of sustained low-efficiency dialysis (SLED) are summarized in **Table VIII-6**. SLED will be performed using standard ultrafiltration-controlled hemodialysis machines that have been adapted to provide reduced dialysate flow rates. Biocompatible synthetic hollow-fiber dialysis membranes will be used for all treatments. Blood flow will be maintained at 200 mL per minute with dialysate flow rates maintained between 100 and 300 mL per minute. Bicarbonate-buffered dialysate will be used for all treatments. The electrolyte composition will be adjusted by the primary treatment team as appropriate. Ultrafiltration goals will be established by the primary treating physicians.

**Table VIII-6**  
**Management of Sustained Low-Efficiency Dialysis (SLED)**

	<i>Conventional Therapy Arm</i>	<i>Intensive Therapy Arm</i>
Treatment Schedule:	3x/week	6x/week
<b><i>Conventional and Intensive Therapy Arms</i></b>		
Hemodialyzer:	Synthetic hollow-fiber membranes	
Blood Flow Rate:	200 mL/min, prescribed by primary treating team	
Dialysate Flow Rate:	100 - 300 mL/min, prescribed by primary treating team	
Dialysate:	Bicarbonate buffered; electrolyte composition prescribed by primary treating team	
Ultrafiltration:	Prescribed by primary treating team	
Anticoagulation:	Prescribed by primary treating team	
Treatment duration:	8 - 16 hours	
Initial Prescribed spKt/V:	1.4	
Target Delivered spKt/V	1.2 – 1.4 per treatment, monitored 3x/week for the first 2 weeks and at least weekly thereafter	

The target dose of therapy for SLED will be the same as for intermittent hemodialysis. The initial dialysis prescription will be based on a target  $\text{spKt}/V_{\text{urea}}$  of 1.4 and should be calculated the same way as for intermittent hemodialysis (Worksheet VIII-1). In calculating the dialysis prescription, it must be recognized that most published dialyzer clearance data are based on higher blood flow and dialysate flow rates than are used during SLED. It will therefore be necessary to adjust the published clearance data based on local experience in the calculation of the initial and subsequent dialysis prescriptions. The actual delivered dialysis dose will be monitored based on blood-side urea-kinetics on the same schedule as described for intermittent hemodialysis (Table VIII-2). The delivered  $\text{spKt}/V_{\text{urea}}$  will be calculated using the same formula as described for intermittent hemodialysis (Worksheet VIII-5). Calculation of  $V_{\text{urea}}$  will be based on adjusted ideal body weight as previously described (Worksheets VIII-2 and VIII-3). The treatment prescription will be modified as necessary to achieve a target  $\text{spKt}/V_{\text{urea}}$  of 1.2 to 1.4

per treatment. Patients randomized to the conventional therapy arm may receive isolated ultrafiltration on non-treatment days, as previously described.

#### **E. Discontinuation of Renal Support**

Renal replacement therapy will be continued as per study protocol until there is recovery of renal function, a decision is made by the patient or surrogate decision-maker to withdraw life-sustaining therapy or the patient dies. All patients who have persistent renal failure when ready for discharge from the acute care setting, or at Day 28 post-randomization, whichever comes first, will be taken off of protocol treatment and will be prescribed further dialysis at the discretion of the treating physicians.

In patients who are oliguric (urine volume < 20 mL/hour), recovery of renal function will be heralded by an increase in urine volume, however in patients who are non-oliguric, urine volume will not be an adequate indicator of recovery of renal function. Similarly, in patients who are being dialyzed on a three-times per week schedule, increased solute clearance may be detected based on a decline in the pre-dialysis blood urea nitrogen or serum creatinine concentrations while in patients dialyzing six-times per week, and patients on CVVHDF, extracorporeal solute clearance will mask changes in blood levels of these markers resulting from increased endogenous clearance.

For this reason, recovery of renal function will need to be objectively assessed in patients with a urine output of > 30 mL/hour based on timed (6-hour) urine collections for creatinine clearance. Clearance studies will be performed three-times per week (on non-dialysis days for patients in the conventional arm), with the urine collection obtained at the time of daily blood work. Creatinine clearance ( $Cl_{Cr}$ ) will be calculated as:

$$Cl_{Cr} = (U_{Cr} \times V / P_{Cr}) \times 2.8 \times 10^{-3}$$

where  $U_{Cr}$  and  $P_{Cr}$  are the urine and serum creatinine concentrations, respectively, in mg/dL and  $V$  is the 6-hour urine volume, in mL (Worksheet VIII-8).

Renal function will be considered to have recovered sufficiently to discontinue renal replacement therapy when the measured creatinine clearance is at least 12 mL/min or there is a spontaneous decline in serum creatinine during the interdialytic period. Since the study end-point for recovery of renal function is defined as a measured creatinine clearance of  $> 20$  mL/min, a repeat measured creatinine clearance needs to be performed in all patients who have discontinued renal replacement therapy with a creatinine clearance between 12 and 20 mL/min on or before day 28 to document a creatinine clearance of  $> 20$  mL/minute.

#### **F. Management of Nutrition**

All patients should be prescribed a nutritional intake that will provide at least 25-30 kcal/kg/day, depending upon mechanical ventilation and other factors. Protein intake should be at least 1.2 g/kg/day. In patients receiving parenteral nutrition, carbohydrate infusion rates should not exceed 5 mg/kg/min. Water-soluble vitamins will be supplemented to replace dialysis-related losses.

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**Table VIII-7**  
**Management of Nutrition**

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Calories	25-30 kcal/kg/day
Protein	$\geq 1.2$ g/kg/day
Carbohydrate	$\leq 5$ mg/kg/min
Vitamins	water-soluble vitamin supplement

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#### **G. Management of Other Medical Care**

The patient's primary physicians will determine the remainder of patient management consistent with established best practices with the management of critically ill patients. In patients with acute lung injury (ALI) or the acute respiratory distress syndrome (ARDS),

mechanical ventilation should be provided using a strategy to minimize barotrauma (e.g., low tidal volume ventilation with a tidal volume of 6 mL per kilogram of predicted body weight adjusted to maintain a peak plateau pressure between 25 and 30 cm of water). Ventilator associated pneumonia will be evaluated and treated in accordance with published clinical practice guidelines and consensus statements. All medications will be dose adjusted for renal failure and renal replacement therapy in accordance with standard dosing guidelines.

#### **H. Withdrawal from Study Protocol**

A patient/surrogate may request to be withdrawn from the study protocol at any time, for any reason, without prejudice. A patient may also be withdrawn from the protocol at the request of his/her physician, for any reason. Patients who withdraw from active study participation will be requested to permit continued data collection for the remainder of the follow-up period. Patients in whom renal replacement therapy is discontinued due to withdrawal of life support should not be considered to have withdrawn from the study protocol unless explicitly requested by the patient or surrogate decision-maker.

#### **I. Protocol Violations**

While adherence to the protocol is of extreme importance, patient safety MUST be our highest priority. We therefore recognize that there may be extenuating circumstances leading to violations of the treatment protocol.

#### ***Additional (Non-Protocol) Hemodialysis or SLED Treatments***

Patients may receive additional hemodialysis treatments as necessitated if life-threatening complications develop. These may include uncontrolled hyperkalemia, severe metabolic acidosis or overt uremic manifestations. The need for an additional treatment does not require

the withdrawal of the patient from the study, but should be discussed with the Study Chairman's office by the next weekday.

### ***Missed Treatments***

Disruption of treatment schedules is not an infrequent occurrence in critically ill patients. For patients who are randomized to the conventional treatment arm, missed hemodialysis/SLED treatments should be made-up the next day with appropriate adjustment in the remaining treatment schedule. For patients who are randomized to the intensive therapy arm, missed treatments will not routinely be made-up. The Study Chairman's office should be contacted by the next weekday to discuss any missed treatments.

### ***Modality of Therapy***

As discussed above, while adhering to the guidelines for selection of modality of renal replacement therapy within each treatment arm is important, situations will arise where these guidelines will conflict with the clinical judgment of the patient's treating physician as to the safest modality of therapy for the individual patient. Deviation from these specific guidelines may be considered on a case-by case basis in order to ensure patient safety. Such deviations DO NOT constitute protocol violations, but need to be reviewed with the Study Chairman, or his designee, within 24 hours. Efforts should be made to convert the patient to the appropriate modality of renal replacement therapy designated by the protocol within 1-2 days.

### **J. Patient Follow-up**

Patient treatment on protocol therapy will last a maximum of 28-days. Patients who have persistent renal failure when ready for discharge from the acute care setting, or at Day 28 post-randomization, whichever comes first, will be taken off protocol treatment and will be prescribed

further dialysis at the discretion of their treating physicians. Follow-up at day-28 for patients who have been discharged from the hospital will be conducted by telephone and/or mail.

Follow-up for the primary study end-point at 60 days and at 1-year will be completed by site staff using telephone and/or mail follow-up. After study closure (i.e., 38 months after study start-up), all remaining 60-day and 1-year follow-up will be performed by staff at the Chairman's Office using telephone and/or mail. Survival data on patients who cannot be contacted will be obtained using the VA Beneficiary Identification and Records Locator System (BIRLS), the National Center for Health Statistics' National Death Index database and the Social Security Administration's Death Master File.

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**Worksheet VIII-1**  
**Calculation of Initial Dialysis Prescription**

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- |                                                                                                                                                                                                                                                                                            |     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| 1. Prescribed $Kt/V$                                                                                                                                                                                                                                                                       | 1.4 |
| 2. Enter $V_{urea}$ from worksheet VIII-2, line 6                                                                                                                                                                                                                                          |     |
| 3. Multiply line 1 by line 2 [ $Kt$ in Liters]                                                                                                                                                                                                                                             |     |
| 4. Multiply line 3 by 1000 [ $Kt$ in mL]                                                                                                                                                                                                                                                   |     |
| <i>To calculate treatment time for a specific dialyzer/blood flow</i>                                                                                                                                                                                                                      |     |
| 5. Select dialyzer                                                                                                                                                                                                                                                                         |     |
| 6. Enter prescribed blood flow rate ( $Q_B$ )                                                                                                                                                                                                                                              |     |
| 7. Enter $K_{urea}$ for selected dialyzer and $Q_B$ (from Coding Appendix; Section XVI, Part G)*                                                                                                                                                                                           |     |
| 8. Calculate treatment duration ( $t$ ) to achieve $Kt/V$ of 1.4 by dividing line 4 by line 7                                                                                                                                                                                              |     |
| <i>To calculate the <math>K_{urea}</math> for a specific treatment time</i>                                                                                                                                                                                                                |     |
| 9. Enter desired treatment duration in minutes ( $t$ )                                                                                                                                                                                                                                     |     |
| 10. Divide line 4 by line 9. Value is the dialyzer urea clearance ( $K_{urea}$ ) necessary to achieve the target $Kt/V$ in the desired treatment duration. Select a dialyzer/blood flow combination from the Coding Appendix; Section XIII, Part G that provides this value for $K_{urea}$ |     |
- 

\*For patients on SLED, the published dialyzer clearances are based on higher blood flow and dialysate flow rates than are used during SLED. The value of  $K_{urea}$  should therefore be reduced from the published values listed in the Coding Appendix based on local experience.

---

**Worksheet VIII-2**  
**Calculation of Volume of Distribution of Urea ( $V_{Urea}$ )**

---

1. Enter adjusted pre-morbid body weight from Worksheet VIII-3, line 6 \_\_\_\_\_
  2. Multiply line 1 by 0.55 \_\_\_\_\_
  3. Enter actual or estimated pre-morbid body weight (kg) \_\_\_\_\_
  4. Enter current body weight (kg) \_\_\_\_\_
  5. Calculate edema weight by subtracting line 3 from line 4. If less than 0, enter 0 \_\_\_\_\_
  6. Calculate  $V_{urea}$  by adding lines 2 and 5 \_\_\_\_\_
-

---

**Worksheet VIII-3**  
**Calculation of Adjusted Pre-Morbid Body Weight**

---

1. Enter actual or estimated pre-morbid body weight (kg) \_\_\_\_\_
  2. Enter Ideal Body Weight from Worksheet VIII-4, line 11 \_\_\_\_\_
  3. Divide line 1 by line 2. If value is  $\leq 1.3$ , use unadjusted pre-morbid weight for all calculations and enter line 1 on line 6. If value is  $> 1.3$ , continue to calculate adjusted pre-morbid weight on line 4. \_\_\_\_\_
  4. Subtract line 2 from line 1 \_\_\_\_\_
  5. Multiply line 4 by 0.25 \_\_\_\_\_
  6. Add lines 2 and 5 \_\_\_\_\_
-

---

**Worksheet VIII-4**  
**Calculation of Ideal Body Weight**

---

1. Enter patient's height in inches \_\_\_\_\_
  2. Subtract 60 from line 1 \_\_\_\_\_
  3. Enter 2.7 if male, by 2.3 if female \_\_\_\_\_
  4. Multiply line 2 by line 3 \_\_\_\_\_
  5. Enter 48 if male, 45.5 if female \_\_\_\_\_
  6. Add lines 4 and 5 \_\_\_\_\_
  7. Enter 1.1 if heavy frame, 1.0 if medium frame or 0.9 if light frame \_\_\_\_\_
  8. Multiply line 6 by line 7 \_\_\_\_\_
  9. Enter adjustment values for amputations using the following scale:

amputation of entire leg	0.186	
above knee amputation	0.110	
below knee amputation	0.070	
foot amputation	0.017	
amputation of entire arm	0.062	
amputation of forearm and hand	0.026	
amputation of hand	0.003	

right upper extremity \_\_\_\_\_

left upper extremity \_\_\_\_\_

right upper extremity \_\_\_\_\_

left upper extremity \_\_\_\_\_

add lines 9a, 9b, 9c, and 9d. Enter 0 if no amputations \_\_\_\_\_
  10. Multiply line 8 by line 9e. \_\_\_\_\_
  11. Calculate Ideal Body Weight by subtracting line 10 from line 8 \_\_\_\_\_
-

---

**Worksheet VIII-5**  
**Calculation of  $spKt/V_{urea}$**

$$-\ln(R - 0.008 \times t) + (4 - 3.5 \times R) \times 0.55 \times UF/V_{urea}$$

---

1. Enter pre-dialysis BUN (mg/dL) \_\_\_\_\_
  2. Enter post-dialysis BUN (mg/dL) \_\_\_\_\_
  3. Divide line 2 by line 1 [R] \_\_\_\_\_
  4. Enter ultrafiltration volume for this treatment, in liters [UF] \_\_\_\_\_
  5. Enter  $V_{urea}$  from Worksheet VIII-2 based on the post dialysis weight from this treatment \_\_\_\_\_
  6. Enter the duration of this treatment in hours [t] \_\_\_\_\_
  7. Multiply line 6 by 0.008 [0.008 x t] \_\_\_\_\_
  8. Subtract line 7 from line 3 [R - 0.008 x t] \_\_\_\_\_
  9. Take the natural logarithm of line 8 [Ln(R - 0.008 x t)] \_\_\_\_\_
  10. Divide line 4 by line 5 [UF/V] \_\_\_\_\_
  11. Multiply line 3 by 3.5 [3.5 x R] \_\_\_\_\_
  12. Subtract line 11 from 4.0 [4 - 3.5 x R] \_\_\_\_\_
  13. Multiply line 12 by 0.55 [(4 - 3.5 x R) x 0.55] \_\_\_\_\_
  14. Multiply line 13 by line 10 [(4 - 3.5 x R) x 0.55 UF/V] \_\_\_\_\_
  15. Subtract line 9 from line 14 [-Ln(R - 0.008 x t) + (4 - 3.5 x R) x 0.55 UF/V] \_\_\_\_\_
-

---

**Worksheet VIII-6**  
**Adjustment of Dialysis Prescription for Measured  $spKt/V_{urea} < 1.2$**

---

1. Enter value of measured  $spKt/V_{urea}$  (Worksheet VIII-5, line 15) \_\_\_\_\_
  2. Enter value of  $V_{urea}$  used in calculating  $spKt/V_{urea}$  (Worksheet VIII-5, line 5) \_\_\_\_\_
  3. Multiply line 2 by 1.96 \_\_\_\_\_
  4. Divide line 3 by line 1 [new target  $Kt$  in Liters] \_\_\_\_\_
  5. Multiply line 4 by 1000 [new target  $Kt$  in mL] \_\_\_\_\_
- To adjust treatment time (t)* \_\_\_\_\_
6. Enter value of dialyzer urea clearance for combination of dialyzer and blood flow rate used in modeled treatment \_\_\_\_\_
  7. Divide line 5 by line 6. Value is new treatment duration in minutes \_\_\_\_\_
- To select dialyzer/blood flow combination with a higher  $K_{urea}$*  \_\_\_\_\_
8. Enter desired treatment duration in minutes ( $t$ ) \_\_\_\_\_
  9. Divide line 5 by line 8. Value is the dialyzer urea clearance ( $K_{urea}$ ) necessary to achieve the target  $Kt/V$  in the desired treatment duration. Select a dialyzer/blood flow combination from the Coding Appendix; Section XVI, Part G that provides this value for  $K_{urea}$ \* \_\_\_\_\_

---

\*For patients on SLED, the published dialyzer clearances are based on higher blood flow and dialysate flow rates than are used during SLED. The value of  $K_{urea}$  should therefore be reduced from the published values listed in the Coding Appendix based on local experience.

---

**Worksheet VIII-7**  
**Calculation of Dialysate and Replacement Fluid Flow Rates for CVVHDF**

---

1. Enter adjusted pre-morbid body weight from Worksheet VIII-3, line 6 \_\_\_\_\_
  2. Enter 10 if patient is randomized to Conventional Therapy or 17.5 if patient is randomized to Intensive Therapy \_\_\_\_\_
  3. Multiply line 1 by line 2. This value is both the dialysate and the replacement fluid flow rate.\* \_\_\_\_\_
- 

\*In patients with adjusted pre-morbid body weight in excess of 115 kg, it may not be possible to maintain a 1:1 ratio of dialysate and replacement fluid given technical limitations of equipment for CVVHDF. For example, using the Prisma® machine, the maximal infusion rate for replacement fluid during CVVHDF is 2,000 mL/hr. If a patient's adjusted pre-morbid body weight is 120 kg, the specified infusion rates would be 2100 mL/hour for both dialysate and replacement fluid. Since the maximal infusion rate for replacement fluid is only 2000 mL/hr, in order to achieve a total infusion rate (e.g., clearance) of 4200 mL/hour, the dialysate rate would be set at 2200 mL/hour.

---

**Worksheet VIII-8**  
**Calculation of Creatinine Clearance**

---

1. Enter volume of 6-hour timed urine collection (mL) [V] \_\_\_\_\_
  2. Enter urine creatinine from timed urine collection (mg/dL) [ $U_{Cr}$ ] \_\_\_\_\_
  3. Enter serum creatinine drawn during timed urine collection (mg/dL) [ $P_{Cr}$ ] \_\_\_\_\_
  4. Multiply line 1 by line 2 [ $U_{Cr} \times V$ ] \_\_\_\_\_
  5. Divide line 4 by line 3 [ $(U_{Cr} \times V) / P_{Cr}$ ] \_\_\_\_\_
  6. Multiply line 5 by 0.0028 [ $(U_{Cr} \times V / P_{Cr}) \times 0.0028$ ] \_\_\_\_\_
-

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## **IX. DATA COLLECTION AND COMPLETION OF CASE REPORT FORMS**

### **A. Timeline for Form Completion and Sending Forms to Coordinating Center**

A copy of the signed informed consent and of the signed release of information forms, and completed originals of the screening, randomization, and subject contact information forms must be sent to the West Haven Coordinating Center (WH CSPCC) **within 24 hours of enrolling** the subject in the study. If the subject was unable to sign the release of information form (Form 14) at the time of his/her enrollment into the study, he/she must sign it at the time he/she is re-consented (after decision making capacity has been regained). Send a copy of the signed release of information form to WH CSPCC within 24 hours of its being signed by the subject. For all other study forms, completed original data forms must be mailed by Federal Express or (USPS with tracking) to the WH CSPCC **within two weeks after completion**. A copy of all completed case report forms (CRF) must be retained in the subject's study file at the participating medical center. In addition, at VA sites, the signed originals of the informed consent and re-consent forms must be placed in the subject's ATN Study file and copies must be placed in the patient's medical record. At non-VA sites, either the signed originals of the informed consent and re-consent forms, or copies of them, as consistent with current policy at each participating non-VA site, must be placed in the subject's ATN Study file and the subject's medical record. Copies of the signed consent and re-consent forms must be provided to the subject and to the Research Office at the participating site (if required by the site IRB). A copy of the informed consent must also be sent to West Haven CSPCC at the time of enrollment.

If at the time of enrollment, the informed consent was signed by the subject's surrogate, then the subject must be re-consented if decision-making capacity has been regained within one year of study enrollment (see Section VI) and a copy of the signed re-consent form must also be

sent to West Haven CSPCC. The informed consent or re-consent form must be signed by the subject or surrogate (by the subject, if re-consenting), by a witness who is not a member of the study team, by the study team member who administers the consent, and by the study Investigator. Please be sure the subject's/surrogate's name and initials and the date are on each page of the informed consent/re-consent. The original of the re-consent form must be filed in the same manner as described above for the informed consent that was obtained at enrollment. Copies of the re-consent form must be made and distributed in the same manner as described above for the informed consent that was obtained at enrollment.

Form 11, the Day 28 Post-Randomization Form, must be completed on study day 28 or at the time the patient exits from the study, whichever comes first. Form 12, the Day 60 Post-Randomization Status Form, must be completed on study day 60 or at the time the patient exits the study, whichever comes first. At study day-60, and after Form 12 has been completed, you will administer the two phone surveys, Forms 17V (for VA sites) or 17N (for non-VA sites) and Forms 19P (to the patient) or 19S (to a surrogate for the patient). At 1-year post-randomization, you will administer the two phone surveys, Forms 18V (for VA sites) or 18 N (for non-VA sites) and Forms 19P (to the patient) or 19S (to a surrogate for the patient).

**The Mailing address of the Coordinating Center where Forms must be sent is:**

**Vanessa McBride  
VA CT Healthcare System  
CSPCC (151A) Building #35  
CSP #530 ATN STUDY  
950 Campbell Avenue  
West Haven, CT 06516**

## B. General Data Form Coding Procedures

A critical aspect of the study is that the data reported from each site must be accurate and collected in a consistent manner. The results of the study depend entirely on the proper collection and recording of the data at the sites. **The participating investigator is responsible for the quality control of all the data submitted from his/her site.** If there are questions or problems concerning form completion or submission, please contact Vanessa McBride at the West Haven Coordinating Center at 203-932-5711, ext 3790.

The forms will be provided to each center as an electronic Portable Document File (PDF). Directions for the completion and submission of PDF versions of the forms are provided below. Hard copies of all CRFs will be printed by CSP and provided to the participating sites upon request. It is preferred that the PDF version of the forms be used for entering of data and for submission to the West Haven CSPCC because this method of data entry will generate fewer queries back to the site than handwritten forms.

Upon receipt of the original CRFs at the West Haven Cooperative Studies Program Coordinating Center (CSPCC), they are scanned directly into a database using optical character recognition software. Do not send copies of data forms to WH CSPCC, except for Form 14 (Release of Information Form) and the consent/re-consent forms. It is very important, if the form is completed by hand, to write legibly using a dark blue or black ballpoint pen. Do not use pencil or ink that will smudge or run. Do not staple multi-page forms because we will be unable to scan stapled forms. Each subject's forms should be paper clipped together before mailing them to CSPCC. The three-digit hospital number, the subject's three-digit identification number, and the subject's initials must be entered at the top of each page on all submitted data

forms. With PDF versions, after the data for these three fields is entered on page 1, the three fields are automatically filled on all subsequent pages.

### Alpha Numeric Fields

For optimum accuracy, please print in capital letters and avoid contact with the edge of the box. The following will serve as an example:

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

### Choice Fields

Only one answer is allowed for choice fields, unless otherwise indicated (e.g., choose all that apply). The most accurate way to answer a choice field is to completely darken the appropriate box. The second best method is to mark the box with an **X**. When marking a box be careful that no stray marks cross over into any other coding boxes that are not intended to be marked. It is important for all choice fields that the mark is clear, dark and within the box provided. Marks outside of the box are not recognized.

For data fields that require descriptions, please try to limit answers to the space provided. If more room is needed, attach a progress note. Avoid writing near or in other coding boxes on the form. All questions should be completed on a CRF unless it states that the question is only to be answered under specific conditions (i.e. “If yes, specify...”).

**Data Corrections:** In adherence to Good Clinical Practice Guidelines, no changes in the original data are permissible without proper documentation as described below. Data corrections/changes should be noted in blank areas on the CRF near the original entry without

obscuring it. The original data should be crossed out with a single line. The date of the change, as well as the initials of the person making the change, must also be noted. For corrections made to choice fields, be certain that the box checked with the corrected information is clearly marked. It is important for all choice fields that the X is dark and within the box, but it is particularly important for data fields that have been changed. **All changes in the data must be recorded on the CRF at the participating center as well as at the West Haven CSPCC.**

**Unavailable Data:** If data are not available, leave blank or mark the N/A box if there is one. This is important for the computer data checking procedure. If a question or a section of a form does not apply to a subject, then leave the corresponding boxes empty. Do not fill boxes with question marks and do not draw lines through any boxes.

**Subject Identification Number:** The subject ID number is a unique three-digit number for each individual subject enrolled in the study. The ID number must be entered in the boxes provided at the top of each data form and on every page. The ID number is generated sequentially by the site, regardless of whether the subject is randomized or not. For example, the Subject ID for the first subject screened at a site will be 001, the second 002 etc. Once that number is used it cannot be used again, i.e., if Subject ID 001 is ineligible for ATN, the next subject screened will be Subject ID 002. If a subject who was screened some time in the past, but was not eligible for randomization then, is subsequently re-screened and is now eligible, the next available sequential number should be used as the Subject ID. Subject ID numbers are unique and should be used **ONLY ONCE.**

**Site Number:** This is the unique identification number for each VA Medical Center. The University sites have been assigned numbers as shown below. The site number must be entered in the boxes provided at the top of each page on all submitted data forms. The 3-digit site numbers for University sites are:

- 901 Cleveland Clinic Foundation
- 902 Johns Hopkins Medical Center
- 903 Massachusetts General Hospital
- 904 University of California, San Francisco
- 905 University of Miami
- 906 University of Pittsburgh
- 907 University of Texas, Houston
- 908 Wake Forest University
- 909 Washington University at St Louis
- 910 MD Anderson Hospital
- 911 Medical College of Georgia

**Subject Initials:** The subject's initials must be entered in the boxes provided at the top of page one of each data form. Whenever possible, please use three initials for subjects, however two initials are acceptable and may be entered in any two of the three boxes provided.

**Dates:** All dates on all forms should be recorded using the six-digit code (mm/dd/yy). The first two digits are for the month, the middle two digits are for the day, and the last two digits for the year. For example, September 6, 2003 should be coded:

0	9	/	0	6	/	0	3
---	---	---	---	---	---	---	---

When entering dates on the PDF versions of the forms, the slashes must be entered between the month, day, and year (See Section C below).

**Staff Initials:** The initials for the site staff member who completes the data form must be entered in the boxes provided at the bottom of the last page of each data form. Whenever possible, please use three initials, however two initials are acceptable and may be entered in any two of the three boxes provided.

### **C. PDF Case Report Forms**

Lap-top computers and printers will be provided to each site to permit printing and entering data into each CRF electronically. CRFs will be provided to participating centers electronically as separate PDF data files. The PDF files will allow sites to complete the data forms on any computer using Adobe Acrobat® Reader version 4.0 or higher. Adobe Acrobat® Reader is available free on-line at [www.adobe.com](http://www.adobe.com). You may not use the full version of Adobe Acrobat to complete the forms. If the PC used to open an ATN study PDF form has an earlier version of Reader, a warning will appear the first time the CRF is opened and a short cut button to the Adobe web site will appear on the top of the form. Prior to installing the downloaded new version of Adobe Reader, the older version of Reader must be uninstalled. A PDF form is opened like any other document in the Windows or Macintosh operating systems. Once the file is opened, be certain that the hand tool is selected from the tool bar across the top of Reader. The default tool after opening a PDF file is the hand tool.

To enter data into a PDF form, use the mouse to get to the first field at the top of the form (Site Number) and enter your site number. After entering the site number, press the Tab key on

the keyboard. The cursor will then automatically move to the next data field (Subject ID). Enter the subject's 3-digit ID number and press the Tab key. The cursor will then move to the third data field. The data entered in the previous field will automatically fall into the appropriate data boxes. Continue entering data until all available information is entered. When responding to a choice field, the Enter key or left-clicking the mouse will mark the selected box and the Tab key will move the cursor to the next choice within the data field. To remove a mark from a choice field, hit the Enter key a second time or left-click the mouse.

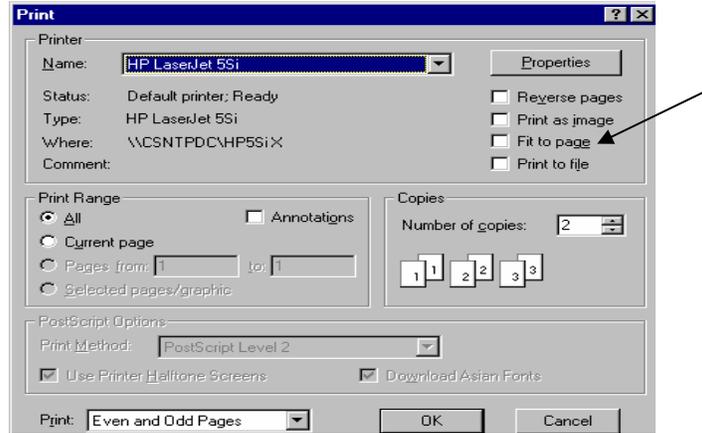
The form can also be navigated by using the mouse. To move to any field on the form, use the mouse to center the cursor in the data field and click. When responding to a choice field with the mouse, move the cursor (the cursor will look like an open hand when navigating around the form outside of data fields) over the box that you intend to mark. Once the picture of the open hand becomes a picture of a hand with the index finger pointing, click the mouse to mark the box. To remove a mark from a choice field, use the mouse to click in the box a second time.

At the time a CRF is filled using Adobe Reader, information for some of the fields may not be available. In that situation, those fields must be left blank. Then print out the form and fill in the blank fields by hand when the information is available. If all the data needed to complete a form is available at one time, complete the CRF using Adobe and then print out the form.

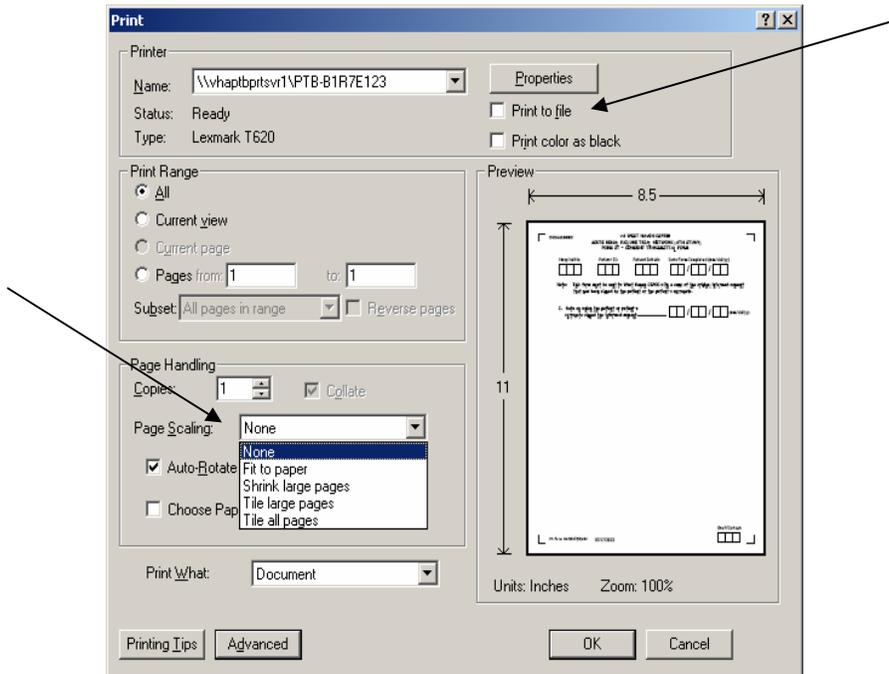
After completing a CRF, send the original of the form to the West Haven CSPCC by FedEx and keep a copy for filing in the subject's study file on site. The data cannot be saved electronically using Adobe Reader.

When printing the PDF forms it is critical that the print settings be set correctly. To view these settings, select "Print" from the 'File' menu in the Adobe Reader program. In Adobe Reader version 4, the 'Fit to Page' box in the upper right hand corner of the print window must

not be checked (see illustration below). In addition, the ‘Print to File’ box must also not be checked. This window is displayed below.



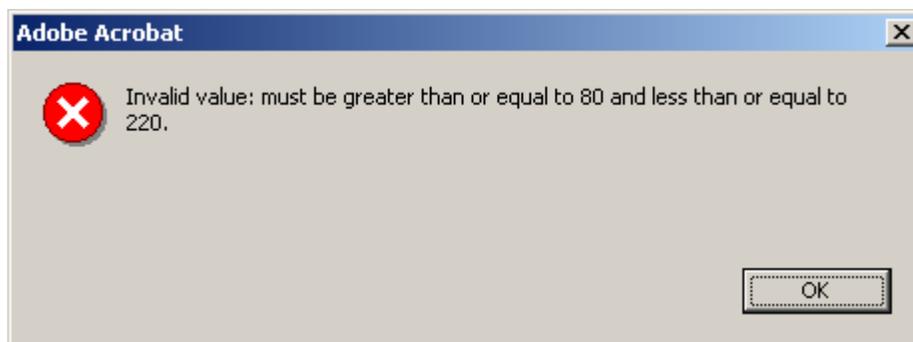
The print window is somewhat different in later versions of Adobe Reader, as shown below. As in version 4.0, the “Print to File” box in the upper right corner must also not be checked. In contrast, however, there is no “Fit to Page” check box. Rather, “Page Scaling” must be set to “None” in the “Page Handling Section in the lower left corner of the Print dialog window



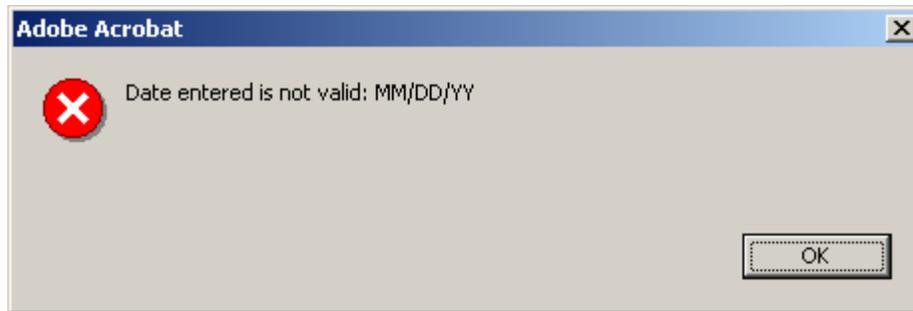
**PDF Data Checks:** Some of the data fields on the PDF versions of the CRFs will have data check programming installed. These checks can include a true date check, a min / max range, a required characters (alpha or numeric) check, and pull down lists. These built in data checks should greatly reduce the number of data queries sent to a site by CSPCC. If a data check prevents the entering of valid data, the field must be left blank until after it is printed, at which point the data should be hand written into the field (on both copies) prior to sending the CRF to the coordinating center.

Data cannot be entered into a data field in the incorrect format i.e., alpha characters cannot be entered in a numeric field. If data is typed into a field that is not in the proper format, a warning noise will be heard and the program will not accept the data.

If data is entered in a field that is out of range, a warning will be displayed that presents the minimum and maximum allowable values. An example of this warning is displayed here.



When entering data in a date field in a PDF version the separators between the month, day and year must be entered. Acceptable separators are / or -. For example, an acceptable date would be 11/28/03 or 11-28-03, while 112803 would not be acceptable. In addition, if the date is not a true MM/DD/YY date, the data will not be accepted. In both these cases the following error message will be displayed.



#### **D. List of CSP530 Data Forms and When to Complete Them**

Specific instructions regarding completion of each individual page of each data form are provided in Section X on the left facing page adjacent to the corresponding form page (right facing page) so that both instructions and form can be viewed at the same time. The forms are listed below and a chart showing when to complete them follows.

Form 1	Screening/Eligibility Form
Form 2	Informed Consent Form (VA Form 10-1086 or non-VA version)
Form 2T	Cover sheet- attach to Consent Form (2) when sent to CSPCC
Form 2A	Informed [Re-]Consent (VA Form 10-1086 or non-VA version )
Form 2R	Cover sheet- attach to Re-Consent Form (2A) when sent to CSPCC
Form 3	Randomization Form
Form 4	Baseline Data Form
Form 5	Subject Contact Information
Form 6	Baseline Scores and Laboratory Values
Form 7	Study Day Scores and Laboratory Values
Form 8	Medications Form
Form 9	Renal Replacement Therapy – Each Treatment
Form 10	Discontinuation of Study Therapy Form
Form 11	Day 28 Post-Randomization Status Form
Form 12	Day 60 Post-Randomization Status Form
Form 13	Study Exit Form
Form 14	Release of Information Form

Form 15	Dialysis Catheter Insertion Form
Form 16	Serious Adverse Event Form
Forms 17N & V	60 Day Follow-up for Non-VA and VA Subjects
Forms 18N & V	12 Month Follow-up for Non-VA and VA Subjects
Forms 19S & P	Health Utilities Index Forms – for use at 60 days and one year
Forms 20N & V	For Subject Use Only – Subject Diary – Not a CRF
Form 21	Biorepository Specimen Confirmation Form

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### Schedule for Completing Data Forms

Study Day:	Screening	Randomization	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Form																
1	X															
2/2T		X														
2R																
2A			To be Completed When Subject Regains Decision-Making Capacity if Initial Consent Provided by Surrogate													
3		X														
4		X														
5		X														
6		X														
7			X	X	X	X	X	X	X	X	X	X	X	X	X	X
8										X <sup>2</sup>						
9			Each Day that Patient Receives Renal Replacement Therapy													
10			Day that Renal Replacement Therapy is Discontinued													
11																
12																
13																
14		X <sup>6</sup>														
15			Each Time a Dialysis Catheter is Inserted/Removed													
16			For Each SAE													
17																
18																
19																
21										X <sup>7</sup>						

<sup>1</sup>Form 2R is to be completed when patient regains decision-making capacity and is re-consented or on Days 28 and 60 and at 1-Year if patient has not regained decision-making capacity. If form is completed because patient has regained decision-making capacity, it does not need to be completed again.

<sup>2</sup>Form 8 is to be completed on Day 8 and Day 28. If patient exits study prior to day 8, the form should be completed at study exit. If patient exits study between days 8 and 28, form should be completed on Day 8 and at study exit

<sup>3</sup>Form 11 should be completed on day that patient exits study if prior to Day 28 or on Day 28.

<sup>4</sup>Form 12 should be completed on day that patient exits study if prior to Day 60 or on Day 60.

<sup>5</sup>Form 13 should be completed on day that patient exits study if prior to Day 60 or on Day 60.

<sup>6</sup>Form 14 is to be completed upon initial consent. If initial consent is provided by a surrogate, this form should be completed and signed by patient when he/she regains decision-making capacity

<sup>7</sup>Form 21 should be completed on day 8, or at study exit, whichever comes first, if no biorepository specimens were collected from the patient. If biorepository specimens were collected from the patient, complete the form when you are ready to ship the bio-repository specimens to MAVERIC. Send the original of this form to WH CSPCC. Make a copy of the form to keep in your study files.

**Schedule for Completing Data Forms (Continued)**

Study Day:	15	16	17	18	19	20	21	22	23	24	25	26	27	28	60	1 Year
Form																
1																
2/2T																
2R														X <sup>1</sup>	X <sup>1</sup>	X <sup>1</sup>
2A	To be Completed When Subject Regains Decision-Making Capacity if Initial Consent Provided by Surrogate															
3																
4																
5																
6																
7							X							X		
8														X <sup>2</sup>		
9	Each Day that Patient Receives Renal Replacement Therapy															
10	Day that Renal Replacement Therapy is Discontinued															
11														X <sup>3</sup>		
12															X <sup>4</sup>	
13															X <sup>5</sup>	
14																
15	Each Time a Dialysis Catheter is Inserted/Removed															
16	For Each SAE															
17															X	
18																X
19															X	X
21																

<sup>1</sup>Form 2R is to be completed when patient regains decision-making capacity and is re-consented or on Days 28 and 60 and at 1-Year if patient has not regained decision-making capacity. If form is completed because patient has regained decision-making capacity, it does not need to be completed again.

<sup>2</sup>Form 8 is to be completed on Day 8 and Day 28. If patient exits study prior to day 8, the form should be completed at study exit. If patient exits study between days 8 and 28, form should be completed on Day 8 and at study exit

<sup>3</sup>Form 11 should be completed on day that patient exits study if prior to Day 28 or on Day 28.

<sup>4</sup>Form 12 should be completed on day that patient exits study if prior to Day 60 or on Day 60.

<sup>5</sup>Form 13 should be completed on day that patient exits study if prior to Day 60 or on Day 60.

<sup>6</sup>Form 14 is to be completed upon initial consent. If initial consent is provided by a surrogate, this form should be completed and signed by patient when he/she regains decision-making capacity.

<sup>7</sup>Form 21 should be completed on day 8, or at study exit, whichever comes first, if no biorepository specimens were collected from the patient. If biorepository specimens were collected from the patient, complete the form when you are ready to ship the bio-repository specimens to MAVERIC. Send the original of this form to WH CSPCC. Make a copy of the form to keep in your study files.

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**X. INSTRUCTIONS FOR CASE REPORT FORMS**

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**A. General Instructions for Form 1 – Screening/Eligibility**

**Enter Hospital Number, Patient ID, Patient Initials, and Date of Screening at the top of the first page of the form and enter the Hospital Number, Patient ID, and Patient initials at the top of pages 2 through 5.**

**When to complete: This form is used to determine if a subject is eligible for this study. This form should be completed and submitted to the West Haven Coordinating Center (WH-CSPCC) every time you screen a patient for entry into the study, regardless of whether the patient gets enrolled in the study.**

**NOTES:**

- 1. In order to screen patients for the study, you may need to obtain a waiver of authorization from your IRB. Each study site is responsible for ensuring that they have obtained any necessary approvals for screening subjects and must provide a copy of the approved plan for patient screening (including any ‘waiver of authorization’) to the WH CSPCC before screening can begin.**
- 2. For patients screened but not enrolled, your IRB may require that you omit the patient’s initials and screening date from the screening form.**
- 3. You must complete the entire form whether or not the patient being screened will ultimately be eligible for entry into the study.**

**Hospital Number:** This is your VA Hospital Number or, for non-VA hospitals, the assigned numbers are:

901 CCF	903 MGH	904 UCSF
905 U. Miami	906 UPMC	907 U. Texas, Houston
908 Wake Forest	909 Washington U., St Louis	
911 Medical College of Georgia		

**Patient ID:** The Patient ID must be a sequential number; for example, the Patient ID for the first patient you screen at your site will be 001, the second patient screened will be 002, and so on. Once that number is used, it cannot be used again; i.e., if Patient 001 is ineligible for the study, the next person who gets screened will be given Patient ID 002. If this patient is eligible, he/she will keep the Patient ID 002 for the duration of the study. If a patient who was screened some time in the past (but was not eligible for randomization at that time) is subsequently re-screened and is now eligible, you should use the next available sequential number as the Patient ID. Patient ID numbers are unique and must be used only ONCE. Remember that the Patient ID is used on every page of every form for the same patient.

**Patient Initials:** Enter the initials of the patient’s first, middle, and last names. If there is no middle initial, enter the first and last initials only. Remember to use the same set of initials for every page of every form for the same patient.

**Screening Date:** This is the date the patient was screened as mm/dd/yy.

NOTE: If the patient is screened and found to be ineligible or the patient/surrogate does not give consent, always complete the remainder of the form and send it to WH CSPCC.

Page 1 of 5

**Instructions for Form 1 – Screening/Eligibility**

**Enter Hospital Number, Patient ID, Patient Initials and Date of Screening.**

**A. INCLUSION CRITERIA – ALL the answers to the six (6) (numbered 1 through 6) questions in BOLD print in this section must be YES in order for the patient to be eligible for entry into the study.**

- 1. Mark ‘yes’ if acute renal failure is clinically consistent with a dx of ATN as defined by item ‘a’ plus (either items ‘b’ or ‘c’) below; otherwise mark ‘no’.**
  - a. Mark ‘yes’ if the clinical setting is acute ischemic or nephrotoxic injury (for definitions, see Section V Table 2 of Ops Manual); mark ‘no’ otherwise.
  - b. Mark ‘yes’ if there has been an increase in serum creatinine of 2 mg/dL or more for males or an increase of 1.5 mg/dL or more for females over baseline values over a period of 4 days or less; mark ‘no’ otherwise.
    1. Enter the gender of the patient.
    2. Enter the lowest serum creatinine within 4 days prior to screening and date obtained as mm/dd/yy. If no serum creatinine was obtained, mark the box labeled ‘no value available’.
    3. Enter the current (at time of screening for study entry evaluation) serum creatinine and date it was obtained as mm/dd/yy.
    4. Enter the date of onset of acute renal failure as mm/dd/yy.
  - c. Mark ‘yes’ if urine output has been less than 20 mL/hour for more than 24 hours (<480mL/24 hours); mark ‘no’ otherwise.
    1. Enter the 24-hour urine volume in mL.
- 2. Mark ‘yes’ if there is clinical need for renal replacement therapy; mark ‘no’ otherwise.**
- 3. Mark ‘yes’ if the patient is receiving care in a critical care unit (e.g., ICU, MICU, SICU, CTICU); mark ‘no’ otherwise.**
  - a. If yes, check the one box that indicates the type of ICU.  
NOTE: If the patient is boarding in an ICU other than the one he/she belongs in, e.g., in a MICU due to absence of SICU beds, please indicate the ICU in which he/she should actually be residing.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 01 - SCREENING/ELIGIBILITY

Hospital No.

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Patient ID

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Patient Initials

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Screening Date (mm/dd/yy)

		/			/		
--	--	---	--	--	---	--	--

**A. INCLUSION CRITERIA (To randomize the patient, items 1-6 must all be YES)**

1. Acute renal failure clinically consistent with a diagnosis of ATN defined as condition (a) plus either condition (b) or (c) below ----- Yes  No

a. Clinical setting of acute ischemic or nephrotoxic injury ----- Yes  No

b. An increase in serum creatinine of  $\geq 2$  mg/dL for males  
or  $\geq 1.5$  mg/dL for females over a period of  $\leq 4$  days ----- Yes  No

1. Gender ----- male  female

2. Lowest serum creatinine within 4 days prior to screening ----- 



 . 



 mg/dL

date obtained ----- 



 / 



 / 



 mm/dd/yy

No value available -----

3. Serum creatinine at screening ----- 



 . 



 mg/dL

date obtained ----- 



 / 



 / 



 mm/dd/yy

4. Date of onset of acute renal failure ----- 



 / 



 / 



 mm/dd/yy

c. Oliguria (average urine output  $< 20$  mL/hour for  $> 24$  hours) ----- Yes  No

1. 24-hour urine volume ----- 



 mL

2. Clinical need for renal replacement therapy ----- Yes  No

3. Receiving care in critical care unit (e.g., ICU, MICU, SICU, CTICU) -----

a. If yes, check one

MICU  SICU  CCU  CTICU  Trauma  Mixed  Other

THIS FORM MUST BE COMPLETED FOR ALL SCREENED PATIENTS

**Instructions for Form 1 – Screening/Eligibility**

**Enter Hospital Number, Patient ID, Patient Initials.**

- 4. Mark ‘yes’ if there is at least one non-renal organ failure or sepsis; i.e., mark ‘yes’ if 1 or more of the conditions ‘a’ through ‘f’ which follow is satisfied; mark ‘no’ otherwise.**
- a. Mark ‘yes’ if PaO<sub>2</sub>/FiO<sub>2</sub> is 300 mmHg or less; mark ‘no’ otherwise. If ‘yes’ is marked, enter the PaO<sub>2</sub> and FiO<sub>2</sub> values (e.g., 100% = 1.00; 50% = 0.50).
  - b. Mark ‘yes’ if the platelet count is less than or equal to 100,000 mm<sup>3</sup>; mark ‘no’ otherwise. If ‘yes’ is marked, enter the platelet count in the boxes provided.
  - c. Mark ‘yes’ if the bilirubin is 2.0mg/dL or more; mark ‘no’ otherwise. If ‘yes’ is marked, enter the bilirubin value in the boxes provided.
  - d. Mark ‘yes’ if the patient has hypotension requiring pressor support for more than 1 hour; mark ‘no’ otherwise.
  - e. Mark ‘yes’ if the Glasgow Coma Scale is 12 or less (see box v. below); mark ‘no’ otherwise.

Calculate the Glasgow Coma Scale Score by adding together the values associated with each of the items ‘ii.’ through ‘iv’. below and enter that sum in the boxes located at item ‘v’.

- i. Mark ‘yes’ if the patient is on sedation; mark ‘no’ otherwise.
- ii. Check the one box that indicates the best eye response.
- iii. Check the one box that indicates the best motor response.
- iv. If the patient is not intubated, check the one box below column (a) that indicates the best verbal response; **OR** if the patient is intubated, then check the one box below column (b) that indicates the best verbal response.
- v. Record the sum of items ii. through iv. in these boxes.

For example, if the best eye response is ‘eye opening to pain’, the score for item ‘ii’ is a ‘2’; if the best motor response is ‘flexion to pain’, the score for item ‘iii’ is a ‘3’; and if patient is not intubated and the best verbal response is ‘converses/confused’, the score for item ‘iv’ is a ‘4’. Add these 3 scores together to obtain ‘9’ for the value of the Glasgow Coma Scale. Enter ‘09’ in item ‘v’ and mark item ‘e’ ‘yes’.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 01 - SCREENING/ELIGIBILITY

Hospital No.

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Patient ID

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Patient Initials

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4. One non-renal organ failure or sepsis; i.e., 1 or more of conditions a-f below is satisfied Yes  No

a. PaO<sub>2</sub>/FiO<sub>2</sub> ≤ 300 mmHg ..... Yes  No

If yes, enter values

PaO<sub>2</sub>

--	--	--

 mmHg;FiO<sub>2</sub>

--	--	--

 . 

--	--

b. Platelet count ≤ 100,000/mm<sup>3</sup> ..... Yes  No

If yes, enter value

--	--	--

 , 

--	--	--

 /mm<sup>3</sup>

c. Bilirubin ≥ 2.0 mg/dL ..... Yes  No

If yes, enter value

--	--	--

 . 

--

 mg/dL

d. Hypotension requiring pressor support for greater than 1 hour ..... Yes  No

e. Glasgow Coma Scale ≤ 12 ..... Yes  No

i. Patient is on sedation? ..... Yes  No

ii. Best Eye Response (check one):

 No eye opening (1) Eye opening to verbal command (3) Eye opening to pain (2) Eyes open spontaneously (4)

iii. Best Motor Response (check one):

 No motor response (1) Withdrawal from pain (4) Extension to pain (2) Localizes pain (5) Flexion to pain (3) Obeys commands (6)

iv. Best Verbal Response (check one)

a. Non-Intubated

 No verbal response (1) Incomprehensible sounds (2) Inappropriate words (3) Converses/Confused (4) Converses/Orientated (5)

b. Intubated

 Generally unresponsive (1) Questionable ability to talk (3) Seems able to talk (5)

v. Record overall score (sum of items ii through iv above)

--	--

**Instructions for Form 1 – Screening/Eligibility**

**Enter Hospital Number, Patient ID, Patient Initials.**

- f. Mark 'yes' if there is sepsis, i.e., proven or suspected infection associated with one or more organ failures; mark 'no' otherwise

If yes,

1. Mark 'yes' if the infection is proven; mark 'no' otherwise.
2. Mark 'yes' if the infection is suspected; mark 'no' otherwise.
3. Enter the code for the infection site (See the coding section of the Ops Manual).

- 5. Mark 'yes' if the patient is 18 years of age or older; mark 'no' otherwise.**

- 6. Mark 'yes' if the informed consent has been signed; mark 'no' otherwise.**

- a. If yes, check the one box that indicates who signed the consent.
- b. If no, check the one box that indicates who refused to sign the consent, or check the last box if no one was available to give consent.

**NOTE: If a surrogate signed the informed consent, please be sure to complete Section C of this form.**

- B. EXCLUSION CRITERIA – ALL the answers to the BOLD items '1' through '15' below must be NO in order to randomize a patient. If any of these 15 items is marked 'yes', the patient may not be randomized.**

- 1. Mark 'yes' if the pre-morbid serum creatinine is greater than 2mg/dL (males) or greater than 1.5mg/dL (females); mark no' otherwise.**

**Note: In the absence of available documentation of baseline renal function, there must be an absence of a past history of chronic kidney disease as well as a renal ultrasound demonstrating normal renal architecture without changes in echogenicity suggesting the presence of chronic kidney disease.**

- a. Enter pre-morbid serum creatinine or check box c. if not available.
- b. Enter date obtained as mm/dd/yy.

- 2. Mark 'yes' if acute renal failure is due to an etiology other than ATN (see Section V Table 4 of Ops Manual); mark 'no' otherwise.**

- a. If 'yes' is marked, enter the 2-digit code for the etiology of the acute renal failure in these boxes (see coding section of the Ops Manual).

- 3. Check 'yes' if more than 72 hours has elapsed since the patient has met BOTH the definition of ARF and the BUN has been greater than 100 mg/dL; mark 'no' otherwise.**

- a. Enter the date on which the patient first met the definition of ARF.

- b. 1. Enter the BUN at the time of screening.  
2. Enter the BUN 3 days prior to screening.

VA WEST HAVEN CSP 530  
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FORM 01 - SCREENING/ELIGIBILITY

Hospital No.  
[ ][ ][ ]

Patient ID  
[ ][ ][ ]

Patient Initials  
[ ][ ][ ]

f. Sepsis defined as proven or suspected infection associated with one or more organ failures. ----- Yes  No

If yes,

1. Proven infection ----- Yes  No

2. Suspected infection ----- Yes  No

3. Site of infection (see Operations manual) ----- [ ][ ]

5. Age  $\geq$  18 years ----- Yes  No

6. Informed consent signed? -----  Yes  No

a. If yes, who signed informed consent (check one)? -----  Patient  Surrogate

If surrogate signed, be sure to complete Section C of this form.

b. If no, (check one). -----  Patient refused  Surrogate refused  Surrogate not available

**B. EXCLUSION CRITERIA (To randomize the patient, items 1-15 must all be NO)**

1. Pre-Morbid serum creatinine  $>2$ mg/dL (males) or  $>1.5$  mg/dL (females) ----- Yes  No

a. Enter pre-morbid serum creatinine ----- [ ][ ] . [ ] mg/dL

b. Date obtained ----- [ ][ ] / [ ][ ] / [ ][ ] mm/dd/yy

c. No value available -----

2. Acute renal failure primarily due to an etiology other than ATN ----- Yes  No

If yes,

a. Etiology code (see Ops Manual) ----- [ ][ ]

3. More than 72 hours since BOTH of the following conditions were met. ----- Yes  No

a. Fulfilled definition of ARF.

1. Date definition of ARF first met ----- [ ][ ] / [ ][ ] / [ ][ ] mm/dd/yy

b. BUN  $> 100$ mg/dL

1. BUN at time of screening ----- [ ][ ][ ] mg/dL

2. BUN 3 days prior to screening ----- [ ][ ][ ] mg/dL

**Instructions for Form 1 – Screening/Eligibility**

**Enter Hospital Number, Patient ID, Patient Initials.**

4. Mark 'yes' if there has already been more than one hemodialysis treatment or if it has been longer than 24 hours since starting CRRT; mark 'no' otherwise.
5. Mark 'yes' if there has been a prior kidney transplant; mark 'no' otherwise.
6. Mark 'yes' if the patient is pregnant; mark 'no' otherwise.
7. Mark 'yes' if the patient is a prisoner; mark 'no' otherwise.
8. Mark 'yes' if the pre-morbid weight is greater than 128.5 kg; mark 'no' otherwise. Enter the pre-morbid weight or an estimate if actual wt N/A.
9. Mark 'yes' if this patient is not a candidate for acute renal replacement therapy; mark 'no' otherwise.
10. Mark 'yes' if this patient is in a moribund state (e.g., expected to survive < 24-48 hours regardless of application of life-support); mark 'no' otherwise.
11. Mark 'yes' if the patient is not expected to survive 28 days because of an irreversible chronic medical condition (e.g., terminal malignancy); mark 'no' otherwise.
12. Mark 'yes' if the goals of therapy for the patient are to provide comfort measures during the dying process rather than to aggressively provide life support; mark 'no' otherwise.
13. Mark 'yes' if the patient is participating in any concurrent interventional trials; mark 'no' otherwise.
14. Mark 'yes' if the patient/surrogate has refused consent for the study; mark 'no' otherwise.
15. Mark 'yes' if the patient's physician has refused to have the patient in the study; mark 'no' otherwise.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 01 - SCREENING/ELIGIBILITY

Hospital No.

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Patient ID

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Patient Initials

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- |                                                                                                                                                                                                                                                                                                                                                                                                                 | Yes                      | No                       |  |  |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|--|--|--|--|
| 4. More than one hemodialysis treatment or longer than 24 hours since starting CRRT -----                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 5. Prior kidney transplant -----                                                                                                                                                                                                                                                                                                                                                                                | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 6. Patient pregnant -----                                                                                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 7. Patient is a prisoner -----                                                                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 8. Pre-morbid weight > 128.5 kg -----                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| a. enter pre-morbid weight <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> . <table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> </table> kg |                          |                          |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                 |                          |                          |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                 |                          |                          |  |  |  |  |
| 9. Non-candidacy for acute renal replacement therapy -----                                                                                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 10. Moribund state -----                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 11. Patient not expected to survive 28 days because of an irreversible chronic medical condition -----                                                                                                                                                                                                                                                                                                          | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 12. Comfort-measures-only status -----                                                                                                                                                                                                                                                                                                                                                                          | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 13. Participation in a concurrent interventional study -----                                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 14. Patient/Surrogate refusal -----                                                                                                                                                                                                                                                                                                                                                                             | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |
| 15. Physician refusal -----                                                                                                                                                                                                                                                                                                                                                                                     | <input type="checkbox"/> | <input type="checkbox"/> |  |  |  |  |

**Instructions for Form 1 – Screening/Eligibility**

**Enter Hospital Number, Patient ID, Patient Initials.**

**C. COMPLETE THIS SECTION IF CONSENT IS BEING PROVIDED BY A SURROGATE**

1. Mark 'yes' if the patient has been deemed by two (2) physicians to be unable to provide informed consent; mark 'no' otherwise.

If 'no' is marked, then surrogate consent cannot be used. Skip to Section D (not Section E, as stated on the form) of this form.

If 'yes' is marked, complete the remainder of this section.

2. Give the first name, middle initial, and last name of the person who signed the surrogate informed consent.
3. Check one of the boxes to indicate the relationship to the patient of the person who signed the surrogate informed consent. If 'other' is checked, specify the relationship to the patient in the box provided.
4. Check one of the boxes to indicate the basis for using the person named in item '2' above as the surrogate consent giver. If 'other' is checked, please specify in the space provided.

- D. Mark 'yes' if the patient is eligible for randomization; mark 'no' otherwise.**

**NOTE: The patient is eligible for randomization if: (1) all of the inclusion criteria are met; (2) none of the exclusion criteria are met; and (3) the informed consent has been signed by the patient or by the patient's surrogate.**

**If the patient is eligible for randomization, complete Form 3, the Randomization Form.**

Enter the date the form was completed as mm/dd/yy and enter the initials of the study staff member who completed the form.



Page 1 of 1

**B. Instructions for Form 2T – Consent Transmittal Form/Cover Sheet**

**Enter Hospital Number, Patient ID, Patient Initials and Date Form Completed**

**When to complete this form: This form must be completed by the coordinator upon enrollment of the patient into the study and must be sent to West Haven CSPCC, along with a copy of the informed consent that was signed by the patient or by the patient's surrogate, within 24 hours of enrolling the patient into the study.**

- I. Enter the date on which the patient or the patient's surrogate signed the informed consent form as mm/dd/yy.

Enter the initials of the staff member completing the form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 2T - CONSENT TRANSMITTAL FORM

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

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Date Form Completed (mm/dd/yy)

		/			/		
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Note: This form must be sent to West Haven CSPCC with a copy of the original informed consent that has been signed by the patient or the patient's surrogate.

I. Date on which the patient or patient's surrogate signed the informed consent.....

		/			/		
--	--	---	--	--	---	--	--

(mm/dd/yy)

Staff Initials

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**C. Instructions for Form 2R – Patient Re-consent Form Cover Sheet**  
**Enter Hospital Number, Patient ID, Patient Initials and Date Form Completed**

**When to complete this form:** For patients who had initial consent provided by a surrogate, recovery of decision-making capacity should be assessed on an ongoing basis and re-consent should be obtained at the earliest possible time that decision-making capacity has been recovered (see Section VI of the Ops Manual). At a minimum, reassessment of decision-making capacity must occur at the end of study treatment (recovery of renal function, discharge, or day-28, whichever comes first), day-60 and at 1-year. Once decision-making capacity has recovered and the patient has been re-consented, further assessment of decision-making capacity is not required – e.g., if at day 7 patient has regained decision-making capacity and has been re-consented, this form does not need to be completed at day-28, day-60, or at 1-year.

**NOTES:**

1. This form and a copy of the signed informed re-consent form must be sent to the West Haven CSPCC within 24 hours of obtaining signed re-consent.
2. If the patient has not signed the re-consent form by study day-28, complete form 2R and send it to WH CSPCC. Similarly, if the patient has not signed the re-consent form by study day 60 or by 1-year, complete a form 2R at that time and send it to WH CSPCC.

**I. Enter the date on which the patient’s decision-making capacity was assessed as mm/dd/yy.**

A. Check the ‘yes’ box if the patient was hospitalized at the time inquiry was made; check the no’ box if the patient was not hospitalized at time inquiry was made.

**II. Check the ‘yes’ box if the patient has regained decision-making capacity; check the ‘no’ box if the patient has not regained decision-making capacity.**

A. If the patient has regained decision-making capacity, the patient must be re-consented for continued participation in the study.

1. Enter the date the patient signed the re-consent form (VA10-1086 or non-VA re-consent form) as mm/dd/yy.
2. Check one of the boxes below depending on whether the patient has consented to continued participation in the study or the patient has not consented to continued participation in the study.

**NOTES:**

1. If patient withdraws consent to continued participation in the study, please complete Form 13 (Study Exit Form).
2. Send this cover sheet and the signed re-consent form to WHCSPCC within 24 hours of obtaining the signed re-consent form

Enter the initials of the staff member completing this form.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 2R - PATIENT RE-CONSENT FORM COVER SHEET

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

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Date Form Completed (mm/dd/yy)

		/			/		
--	--	---	--	--	---	--	--

I. Date on which the patient's decision-making capacity was assessed.-----

		/			/		
--	--	---	--	--	---	--	--

(mm/dd/yy)

A. Was patient hospitalized at time of inquiry?----- Yes  No

II. Has the patient regained decision-making capacity? ----- Yes  No

A. If the patient has regained decision-making capacity, the patient must be re-consented for continued participation in the study.

1. Date patient signed Re-consent Form (VA Form 10-1086) -----

		/			/		
--	--	---	--	--	---	--	--

(mm/dd/yy)

2. Check one of the boxes below

- Patient consented to continued participation in the study.
- Patient has not consented to continued participation in the study.

Notes: 1. If patient withdraws consent to continued participation in the study, please complete Form 13 (Study Exit Form).

2. Send this cover sheet and the signed re-consent form to WHCSPCC within 24 hours of receiving the signed re-consent form.

Staff Initials

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**D. Instructions for Form 3 – Randomization Form**

**Enter Hospital Number, Patient ID, Patient Initials, and Date of Randomization.**

**When to complete this form: This form should be completed after the eligibility of the patient has been determined, the informed consent has been signed, and you are ready to randomize the patient into the study. Do not complete it for patients who do not meet the eligibility criteria, have met one or more of the exclusion criteria, do not fit in the enrollment window, or for whom you do not have a signed informed consent.**

- A. Mark 'yes' if the patient meets all the inclusion criteria on the screening form and if 'no' has been answered for all the exclusion criteria; mark 'no' otherwise.
- B. Mark 'yes' if the informed consent form has been signed by either the patient or the patient's surrogate; mark 'no' otherwise. If 'yes' is marked, enter the date that the consent form was signed as mm/dd/yy.
- C. Check the appropriate **one** of the 5 boxes. The box checked is the Cardiovascular Organ Failure Score that you will use when randomizing the patient.
- D. Mark 'yes' if the urine output has been less than 20 mL/hr for more than 24 hours (<480ml/24 hours); mark 'no' otherwise. The answer to this question will be the same as the one you will give when you are asked about oliguric status when randomizing the patient.
- E. To Randomize the patient:
  1. Call the phone randomization system directly at (410)-642-1175 as described in Section VII of the Ops Manual. Answer the questions asked by the phone randomization system and receive the treatment assignment.
  2. FAX the screening form, the signed informed consent, and **the completed Form 03** to Vanessa McBride/CSP530 at West Haven CSPCC. The FAX number is: (203) 937-3858. Please be sure to put Vanessa's name on the FAX cover sheet.
- F. Mark the appropriate treatment group assignment box below once you have been given the treatment assignment by the phone randomization system. If the patient has been assigned to the Conventional Group, dialysis will be on a 3-day/week basis. If the patient has been assigned to the Intensive Group, dialysis will be on a 6-day/week basis.

**NOTE: The originals of the screening form (Form 01) and of the randomization form (Form 03) and a copy of the signed informed consent must also be mailed to West Haven as soon as possible after the patient has been randomized.**

Enter the date the form was completed and the initials of the staff member completing the form.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 03 - RANDOMIZATION

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

Randomization Date (mm/dd/yy)

[ ][ ] / [ ][ ] / [ ][ ]

A. Patient is Eligible ..... Yes  No

B. Patient/Surrogate signed informed consent ..... Yes  No

1. Date consent form signed

[ ][ ] / [ ][ ] / [ ][ ] mm/dd/yy

C. SOFA Cardiovascular Organ Failure Score (choose one)

0 = No hypotension

1 = MAP < 70 mmHg off pressors

2 = Dopamine ≤ 5mcg/kg/min or dobutamine (any dose) for at least one hour

3 = (Dopamine > 5mcg/kg/min and ≤ 15mcg/kg/min) or (epinephrine ≤ 0.1mcg/kg/min or norepinephrine ≤ 0.1mcg/kg/min) or (phenylephrine ≤ 0.1mcg/kg/min)

4 = (Dopamine > 15mcg/kg/min) or (epinephrine > 0.1mcg/kg/min) or (norepinephrine > 0.1mcg/kg/min) or (phenylephrine > 0.1mcg/kg/min) or (any dose of vasopressin)

D. Oliguric (average urine output <20 mL/hr for >24 hours) ..... Yes  No

E. TO RANDOMIZE THE PATIENT (See Operations Manual):

1. Call the phone randomization system at Perry Point CSPCC (410/642-1175) to receive the treatment assignment (see Ops Manual) and complete Section F below.

2. Fax Form 01 (Screening Form), the signed informed consent, and the completed Form 03 to Vanessa McBride/CSP530 at the West Haven CSPCC. The Fax number is (203)937-3858.

F. Treatment Group Assignment (check one)  CONVENTIONAL  INTENSIVE

Date of Form Completion (mm/dd/yy)

[ ][ ] / [ ][ ] / [ ][ ]

Staff Initials

[ ][ ][ ]

**E. Instructions for Form 4 – Baseline Form**

**Enter Hospital Number, Patient ID, Patient Initials, and Date of Form Completed.**

**When to complete this form: This form should be completed between the time the patient is randomized and before the patient is started on the first study treatment.**

**A. Primary Diagnosis at Time of Onset of ARF**

1. Enter the diagnosis in the boxes provided.
2. Mark ‘yes’ if the patient status is post “open” surgical procedure; mark ‘no’ otherwise. “Open” surgical procedure includes both conventional and laparoscopic surgery, but does not include endovascular or endoscopic procedures.

**B. Primary Treating Service:** Check one of the choices given for primary treating service. If ‘other’ is checked, specify the service in the box provided.

**C. ARF Information**

1. Indicate the etiology of the acute renal failure by answering ‘yes’ to at least one of the following;
  - a. Mark ‘yes’ if the etiology of ARF is ischemic ATN; mark ‘no’ otherwise.
  - b. Mark ‘yes’ if the etiology of ARF is nephrotoxic (e.g., radio-contrast, aminoglycoside, rhabdomyolysis) ATN; mark ‘no’ otherwise.
  - c. Mark ‘yes’ if the etiology of ARF is sepsis induced ATN; mark ‘no’ otherwise;
  - d. Mark ‘yes’ if the etiology of ARF is multifactorial; mark ‘no’ otherwise.

**D. Hospitalization History**

1. Enter the admission date for the current hospitalization as mm/dd/yy.
2. Enter the admission date for the current ICU stay as mm/dd/yy.
3. Mark ‘yes’ if the patient was transferred from an outside hospital; mark ‘no’ otherwise.
4. Mark **only one** of the 4 choices to indicate from where the patient was admitted. If you mark ‘Other’, then specify the place in the text box provided.

**E. Demographic Information**

1. Enter the date of birth as mm/dd/yy.
2. Enter the age of the patient in years.
3. Mark the box that indicates the gender of the patient.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 04 - BASELINE FORM

Hospital No.	Patient ID	Patient Initials	Date Form Completed (mm/dd/yy)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>

COMPLETE THIS FORM BETWEEN RANDOMIZATION AND FIRST STUDY TREATMENT

A. Primary Diagnosis at Time of Onset of ARF

1. Diagnosis

2. Is patient post "open" surgical procedure?----- Yes  No

B. Primary treating service (check one)

Medical  Surgical  Other, specify

C. ARF Information

1. Etiology of Acute Renal Failure:

- a. Ischemic-----Yes  No
- b. Nephrotoxic-----Yes  No
- c. Sepsis-----Yes  No
- d. Multifactorial-----Yes  No

D. Hospitalization History

1. Date of Current Hospital Admission-----  /  /  mm/dd/yy

2. Date of ICU Admission-----  /  /  mm/dd/yy

3. Was patient transferred from an outside hospital?-----Yes  No

4. Patient was admitted from: (choose one)

- Home
- Skilled Nursing Facility
- Assisted Living Facility
- Other (specify)

E. Demographic Information

1. Date of birth-----  /  /  (mm/dd/yy)

2. Age (years)-----  years

3. Gender-----  Male  Female

**Instructions for Form 4 – Baseline Form**

**Enter Hospital Number, Patient ID, Patient Initials.**

4. Check the most appropriate one of the boxes to indicate the patient's racial/ethnic origin.

**F. Military Service History (This information must be collected for all study patients)**

1. Mark 'yes' if the patient has ever served in the U.S. military; mark 'no' if the patient has never served in the U.S. military; mark 'N/A' if this information is not available. If 'yes' is marked, complete the remainder of Section F. If 'no' or 'N/A' is marked, skip to Section G.
2. Mark 'yes' if the patient has ever been on active duty; mark 'no' otherwise. Mark 'N/A' if this information is not available.
3. Mark 'yes' if the patient's only military service has been in the reserves; mark 'no' otherwise. Mark 'N/A' if this information is not available.
4. Check all the wars or conflicts during which the patient has served or check 'information not available'. If 'other' is checked, please specify the war or conflict in the space provided.
5. Mark 'yes' if the patient ever served outside the US; mark 'no' otherwise. Mark 'N/A' if this information is not available.
6. Check all the branches of the service in which the patient served.

**G. Medical History – NOTE: For items 1 through 11 in this section, if the 'yes' box is not checked for a condition, please be sure to check either the 'no' box for that condition or the 'N/A' box if the information is not available.**

1. Cardiovascular Disease
  - a. Mark 'yes' if the patient has a history of myocardial infarction documented by enzyme changes or persistent wall motion abnormalities. The presence of electrocardiographic changes without other correlates of myocardial infarction is not considered sufficient documentation.
  - b. Mark 'yes' if the patient has a history of angina.
    - i. If 'yes' to angina, mark 'yes' if the patient has had symptoms at rest.
  - c. Mark 'yes' if the patient has had congestive heart failure (CHF) defined based on a history of exertional or paroxysmal nocturnal dyspnea responsive to medical therapy or documented decreased left ventricular ejection fraction (<35%).
    - i. If 'yes' to CHF, mark 'yes' if the patient has had symptoms at rest.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 04 - BASELINE FORM

Hospital No.

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Patient ID

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Patient Initials

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4. Racial/Ethnic Origin (check one)

- White, not of Hispanic Origin
- Black, not of Hispanic Origin
- Hispanic
- Asian
- Pacific Islander
- American Indian/Alaskan Native
- Other

F. Military Service History

1. Has the patient ever served in the U.S. military?.....Yes  No  N/A\*   
 If yes, complete rest of Section F  
 If no or N/A, skip to Section G

2. Active duty.....Yes  No  N/A\*

3. Reserves only.....Yes  No  N/A\*

4. When did the patient serve (check all that apply)

- World War I
- World War II
- Korean Conflict
- Vietnam Conflict
- Balkans Conflict
- Afghanistan Conflict
- Gulf War
- Peace Time
- Information not available
- Other War/Conflict (specify)

--

5. Did the patient serve outside the United States?.....Yes  No  N/A\*

6. What was the branch of service (check all that apply)

- Army
- Air Force
- Navy
- Marines
- Coast Guard
- National Guard
- Information not available

G. Medical History

	Yes	No	N/A*
1. Cardiovascular disease			
a. Documented myocardial infarction.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Angina.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Symptoms at rest.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Congestive Heart Failure.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Symptoms at rest.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*N/A means Information Not Available

**Instructions for Form 4 – Baseline Form**

**Enter Hospital Number, Patient ID, Patient Initials.**

2. Mark 'yes' if the patient has had peripheral vascular disease defined as intermittent claudication, history of angioplasty or bypass surgery, gangrene, acute arterial insufficiency or amputation due to vascular disease, or has an untreated thoracic or abdominal aortic aneurysm that is 6cm or greater.
3. Cerebrovascular Disease
  - a. Mark 'yes' if the patient has had TIA's.
  - b. Mark 'yes' if the patient has had CVA with minor or no residual defect.
  - c. Mark 'yes' if the patient has had CVA with any residual hemiplegia'.
4. Mark 'yes' if the patient has dementia or cognitive deficits.
5. Chronic Pulmonary Disease
  - a. Mark 'yes' if patient has chronic hypoxemia.
  - b. Mark 'yes' if the patient has hypercapnia.
  - c. Mark 'yes' if the patient has secondary polycythemia.
  - d. Mark 'yes' if the patient has severe pulmonary hypertension.
  - e. Mark 'yes' if the patient has chronic ventilator dependence.
6. Mark 'yes' if the patient has had a connective tissue disorder such as systemic lupus erythematosus, polymyositis, mixed connective tissue disease, rheumatoid arthritis, or vasculitis.
7. Mark 'yes' if the patient has a history of peptic ulcer disease, with or without a history of bleeding.
8. Chronic liver disease
  - a. Mark 'yes' if the patient has a history of mild liver disease including chronic hepatitis or cirrhosis without portal HTN.
  - b. Mark 'yes' if the patient has a history of moderate or severe liver disease, including cirrhosis with portal HTN, with or without variceal bleeding.
  - c. Mark 'yes' if the patient has had episodes of hepatic encephalopathy.
9. Diabetes mellitus
  - a. Mark 'yes' if the patient has a history of diabetes mellitus that is treated with diet alone.
  - b. Mark 'yes' if the patient has a history of diabetes mellitus requiring therapy with oral hypoglycemic agents or insulin.
  - c. Mark 'yes' if the patient has end-organ disease due to diabetes mellitus, including retinopathy, neuropathy, or nephropathy.
10. Malignancy
  - a. Mark 'yes' if the patient has a history of a non-hematologic malignancy without metastatic disease (does not include non-melanoma skin cancer).
  - b. Mark 'yes' if the patient has a history of a non-hematologic malignancy with metastatic disease.
  - c. Mark 'yes' if the patient has a history of leukemia or lymphoma.
11. Immune-suppressed
  - a. Mark 'yes' if the patient is HIV positive but does not have AIDS.
  - b. Mark 'yes' if the patient has clinical AIDS.
  - c. Mark 'yes' if the patient is on immunosuppressant (prednisone > 20mg/day for more than 2 weeks or other immunosuppressive therapy).
  - d. Mark 'yes' if the patient has another immune compromised state.

VA WEST HAVEN CSP 530  
 ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
 FORM 04 - BASELINE FORM

Hospital No.

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Patient ID

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Patient Initials

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- |                                                                                                             | Yes                      | No                       | N/A*                     |
|-------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|
| 2. Peripheral Vascular Disease (includes untreated aortic aneurysm >= 6cm) -----                            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Cerebrovascular Disease                                                                                  |                          |                          |                          |
| a. TIA's -----                                                                                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. CVA with minor or no residual defect -----                                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. CVA with residual hemiplegia -----                                                                       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Dementia (includes cognitive deficits) -----                                                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Chronic Pulmonary Disease                                                                                |                          |                          |                          |
| a. Chronic hypoxemia -----                                                                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Hypercapnia -----                                                                                        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Secondary polycythemia -----                                                                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Severe pulmonary hypertension -----                                                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Chronic ventilator dependence -----                                                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Connective Tissue Disorder -----                                                                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Peptic Ulcer Disease (with or without bleeding) -----                                                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Chronic liver disease                                                                                    |                          |                          |                          |
| a. Mild liver disease - chronic hepatitis<br>or cirrhosis without portal HTN -----                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Moderate or severe liver disease<br>(cirrhosis with portal HTN, with or without variceal bleeding) ----- | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Encephalopathy -----                                                                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Diabetes Mellitus                                                                                        |                          |                          |                          |
| a. Treated with diet alone -----                                                                            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Treated with oral hypoglycemic agents or insulin -----                                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. With end-organ disease (retinopathy or neuropathy) -----                                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Malignancy                                                                                              |                          |                          |                          |
| a. Solid tumor without metastases -----                                                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Solid tumor with metastases -----                                                                        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Leukemia or lymphoma -----                                                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Immune-suppressed                                                                                       |                          |                          |                          |
| a. HIV+ (not AIDS) -----                                                                                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. AIDS (not just HIV+) -----                                                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. On immunosuppression -----                                                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Other immune compromised state -----                                                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

\*N/A means Information Not Available

**Instructions for Form 4 – Baseline Form**

**Enter Hospital Number, Patient ID, Patient Initials.**

**H. Physical Exam**

1. Enter the pre-morbid (edema-free) body weight in kilograms.
2. Enter the pre-morbid height in inches.
3. Enter ideal body weight in kilograms.
  - a. If the actual pre-morbid body weight is greater than 30% above the ideal body weight, enter the adjusted pre-morbid weight (see worksheets VIII-3 and VIII-4 in Section VIII of the Operations Manual).
4. Enter the systolic and diastolic blood pressure in mmHg measured at the time of randomization.

**I. Nutrition Management (at time of randomization).**

1. Mark 'yes' if the patient is NPO; mark 'no' otherwise.
2. Mark 'yes' if oral supplements are being used; mark 'no' otherwise.
  - a. Enter the code for the type of oral supplement being used (see the coding section of the Operations Manual).
  - b. Enter the volume of undiluted oral supplement actually administered (mL/day).
3. Mark 'yes' if tube feeding is being used; mark 'no' otherwise.
  - a. Enter the formulation code for the tube feeding (see the coding section of the Operations Manual)
  - b. Enter the volume of undiluted tube feed actually administered (mL/day).
4. Mark 'yes' if the method of nutrition management is TPN; mark 'no' otherwise.
  - a. Enter the number of calories per day administered.
  - b. Enter the number of grams of protein per day administered.
  - c. Enter the number of grams of lipids per day administered.

**NOTE: Be sure to also complete the Patient Contact Information Form (Form 5), the Baseline Scores and Laboratory Values Form (Form 6) and the Release of Information Form (Form 14) for this patient. Mail the originals of Form 4, Form 5, Form 6, and a copy of the signed Form 14 to West Haven CSPCC as soon as possible.**

Fill in the initials of the staff member who has completed this form.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 04 - BASELINE FORM

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

H. Physical Exam

1. Pre-morbid Body Weight ..... [ ][ ][ ] . [ ] kg

2. Pre-morbid Height ..... [ ][ ] inches

3. Ideal Body Weight ..... [ ][ ][ ] . [ ] kg

a. If actual pre-morbid body weight is >30% above ideal body weight, enter  
adjusted pre-morbid weight (see Ops Manual) [ ][ ][ ] . [ ] kg

4. Blood Pressure

Systolic BP [ ][ ][ ] mmHg

Diastolic BP [ ][ ][ ] mmHg

I. Nutrition Management

1. NPO ..... Yes  No

2. Oral Supplements ..... Yes  No

a. Type of Supplement (see Ops Manual for codes) ..... [ ][ ][ ]

b. Number of mL administered per day ..... [ ][ ][ ][ ] mL

3. Tube Feed ..... Yes  No

a. Formulation (see Ops Manual for codes) ..... [ ][ ][ ]

b. Number of mL administered per day ..... [ ][ ][ ][ ] mL

4. TPN ..... Yes  No

a. Calories/day ..... [ ][ ][ ][ ]

b. Protein/day ..... [ ][ ][ ] grams

c. Lipids/day ..... [ ][ ][ ] grams

NOTE: Complete the Patient Contact Information Form (Form 05), Baseline Scores and  
Labs Form (Form 06) and Release of Information Form (Form 14) for this patient.

Staff Initials [ ][ ][ ]

**F. Instructions for Form 5 – Patient Contact Information Form  
Enter Hospital Number, Patient ID, Patient Initials, and Date Form Completed.**

**When to complete this form: This form should be completed as soon as possible after the subject has been randomized.**

**A. Patient information**

1. Enter the patient's social security number.
2. Enter the patient's first name, middle initial and last name.
3. Enter the patient's mailing address as number and street name. Enter an apartment number if applicable.
4. Enter the city, state, and zip code for the patient's address.
5. Mark 'yes' if the patient has a phone; mark 'no' otherwise.
  - a. Enter the patient's home phone number if there is one, including the area code.
  - b. Enter the patient's business phone number if there is one, including the area code.
6. Enter the patient's email address if there is one.



**Instructions for Form 5 – Patient Contact Information Form**

**Enter Hospital Number, Patient ID, Patient Initials, and Date Form Completed.**

**B. Contact/Next of Kin**

1. Enter the first name, middle initial, and last name of the contact person for the patient or of the patient's next of kin. This should be the person we can contact to find the patient if the information in Section 'A' above becomes obsolete or is incorrect.
2. Enter the contact's mailing address as number and street name. Enter an apartment number if applicable.
3. Enter city, state, and zip code for the contact's address.
4. Mark 'yes' if the contact has a phone; mark 'no' otherwise.
  - a. Enter the contact's home phone number if there is one, including the area code.
  - b. Enter the contact's business phone number if there is one, including the area code.
5. Enter the email address for the contact if there is one.
6. Mark the **one box** that best describes the relationship of the contact person to the patient. If the 'other' box is marked, please specify the relationship of the contact person to the patient in the box provided.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)

FORM 05 - PATIENT CONTACT INFORMATION

Hospital No.

Grid for Hospital No.

Patient ID

Grid for Patient ID

Patient Initials

Grid for Patient Initials

B. Contact/Next of Kin

1. First Name

Grid for First Name

MI

Grid for MI

Last Name

Grid for Last Name

2. Mailing Address (Number and Street Address)

Grid for Mailing Address (Line 1)

Apartment Number

Grid for Apartment Number

Grid for Mailing Address (Line 2)

3. City

Grid for City

State

Grid for State

Zip Code

Grid for Zip Code

4. Does contact have a phone?

Yes

No

a. Home phone

Grid for Home phone

b. Business/other phone

Grid for Business/other phone

5. Email address

Grid for Email address

6. Relationship to Patient (choose one)

Spouse/Partner  Friend

Parent  Other relative

Sibling  Other

Child

Grid for Other relationship

**Instructions for Form 5 – Patient Contact Information Form**

**Enter Hospital Number, Patient ID, Patient Initials, and Date Form Completed.**

**C. Contact information for the surrogate if the surrogate is not the person whose information was given in item ‘B’ above.**

1. Enter the surrogate’s first name, middle initial, and last name.
2. Enter the surrogate’s mailing address as number and street name. Enter the apartment number, if applicable.
3. Enter the city, state, and zip code for the surrogate’s address.
4. Mark ‘yes’ if the surrogate has a phone; mark ‘no’ otherwise.
  - a. Enter the surrogate’s home phone number if there is one, including the area code.
  - b. Enter the surrogate’s business phone number if there is one, including the area code.
5. Enter the email address for the surrogate if there is one.
6. Mark the **one box** that best describes the relationship of the surrogate to the patient. If the ‘other’ box is marked, please specify the relationship of the surrogate to the patient in the box provided.

Enter the initials of the staff member who completed the form.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)

FORM 05 - PATIENT CONTACT INFORMATION

Hospital No.

Grid for Hospital No.

Patient ID

Grid for Patient ID

Patient Initials

Grid for Patient Initials

C. CONTACT INFORMATION FOR SURROGATE IF DIFFERENT THAN PERSON IN ITEM B.

1. First Name

Grid for First Name

MI

Grid for MI

Last Name

Grid for Last Name

2. Mailing Address (Number and Street Address)

Grid for Mailing Address (Line 1)

Apartment Number

Grid for Apartment Number

Grid for Mailing Address (Line 2)

3. City

Grid for City

State

Grid for State

Zip Code

Grid for Zip Code

4. Does contact have a phone?

Yes

No

a. Home phone

Phone number grid for home phone

b. Business/other phone

Phone number grid for business/other phone

5. Email address

Grid for Email address

6. Relationship to Patient(choose one)

- Spouse/Partner, Friend, Parent, Other relative, Sibling, Other, Child

Grid for relationship details

Grid for Staff Initials

**G. Instructions for Form 6 – Baseline Scores and Laboratory Values**  
**Enter Hospital Number, Patient ID, Patient Initials, and Date Form Completed.**

**When to complete this form: \*\*\* IT IS IMPORTANT THAT ALL THE DATA ON THIS FORM IS THE MOST RECENT DATA THAT WAS COLLECTED BEFORE THE PATIENT STARTED THE FIRST TREATMENT ON THE STUDY PROTOCOL.**

**A. Vital Signs**

1. Enter the patient's temperature (oral, rectal, tympanic, or core, but **not** cutaneous/axillary).
  - a. Scale on which temperature was read – mark the 'Celsius' box if the temperature was read in degrees Celsius; mark the 'Fahrenheit' box if the temperature was read in degrees Fahrenheit.
2. Enter the heart rate in beats per minute.
3.
  - a. Enter the spontaneous respiratory rate in breaths per minute.
  - b. Enter the ventilator setting in breaths per minute or, if the patient is not on a ventilator, check the 'not on ventilator' box.
4. Enter the blood pressure as systolic/diastolic in mmHg. BP should be the lowest value recorded in the 24-hour period prior to initiation of study therapy.
5. Enter the mean arterial pressure in mmHg as read directly from a monitoring system. Check the 'N/A' box if no such reading is available for MAP.
6. Enter the SaO<sub>2</sub> value as a percent.

**B. Mark 'yes' if the patient is intubated or if the patient has a tracheotomy; mark 'no' otherwise.**

**C. Mark 'yes' if the patient is on mechanical ventilation; mark 'no' otherwise.**

If the patient is on mechanical ventilation (MV),

1. Specify mode (Choose one).

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 06 - BASELINE SCORES AND LABORATORY VALUES

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

--	--	--

Date Form Completed (mm/dd/yy)

		/			/		
--	--	---	--	--	---	--	--

NOTE: ALL DATA ON THIS FORM SHOULD BE THE MOST RECENT DATA PRIOR TO INITIATION OF THE FIRST TREATMENT ON PROTOCOL.

## A. Vital Signs

1. Temperature (in degrees C or F) ..... 

--	--	--

 . 

--

 Degrees

a. Scale used (check one) .....  Celsius  Fahrenheit

2. Heart Rate ..... 

--	--	--

 beats/min

3. Respiratory Rate

a. spontaneous ..... 

--	--

 breaths/min

b. ventilator setting ..... 

--	--

 breaths/min  not on ventilator

4. Blood Pressure (systolic/diastolic) ..... 

--	--	--

 / 

--	--	--

 mmHg

5. Mean Arterial Pressure as read from monitoring system 

--	--	--

 mmHg  N/A\*

6. Transcutaneous Hemoglobin Oxygen Saturation (SaO<sub>2</sub>) 

--	--	--

 %

B. Patient intubated or has tracheostomy? ..... Yes  No

C. Patient on mechanical ventilation? ..... Yes  No

If Yes,

1. Specify mode (choose one):

Volume-targeted (AC, IMV, or IMV with PS; also answer question C.2.)

Pressure Control (PC; also answer question C.3.)

Pressure Support (PS; also answer question C.4.)

Other invasive mechanical ventilation (intubated)

Non-invasive mechanical ventilation (non-intubated)

**Instructions for Form 6 – Baseline Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials.**

**C. Patient on mechanical ventilation? (continued)**

2. If the patient is on volume targeted MV (AC, IMV, or IMV with PS), specify:
  - a. Enter Set tidal volume in ml.
  - b. Enter Plateau airway pressure in cm.
  - c. Enter PEEP in cm
  - d. Enter FiO<sub>2</sub> in %.
3. If the patient is on Pressure Control (PC) ventilation, specify:
  - a. Enter Set inspiratory pressure in cm.
  - b. Enter Tidal volume in ml.
  - c. Enter PEEP in cm.
  - d. Enter FiO<sub>2</sub> in %.
4. If the patient is on Pressure Support (PS) ventilation, specify:
  - a. Enter Pressure support level in cm.
  - b. Enter Tidal volume in ml.
  - c. Enter PEEP in cm.
  - d. Enter FiO<sub>2</sub> in %.

**D. Arterial Blood Gas-mark the 'yes' box if arterial blood gas was obtained; mark the 'no' box otherwise. If the 'yes' box is marked, enter values for the 4 items below.**

1. Enter the value for arterial pH.
2. Enter the value for PaCO<sub>2</sub> in mmHg.
3. Enter the value for PaO<sub>2</sub> in mm Hg.
4. Enter the value for FiO<sub>2</sub> in %.

Hospital No.

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Patient ID

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Patient Initials

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C. Patient on mechanical ventilation? (continued)

2. If the patient is on volume targeted MV (AC, IMV, or IMV with PS), specify:

a. Set tidal volume ..... 

--	--	--	--

 mL

b. Plateau airway pressure ..... 

--	--

 cm H<sub>2</sub>O

c. PEEP ..... 

--	--

 cm H<sub>2</sub>O

d. FiO<sub>2</sub> ..... 

--	--	--

 %

3. If the patient is on Pressure Control (PC) ventilation, specify:

a. Set inspiratory pressure ..... 

--	--

 cm H<sub>2</sub>O

b. Tidal volume ..... 

--	--	--	--

 ml

c. PEEP ..... 

--	--

 cm H<sub>2</sub>O

d. FiO<sub>2</sub> ..... 

--	--	--

 %

4. If the patient is on Pressure Support (PS) ventilation, specify:

a. Pressure support level ..... 

--	--

 cm H<sub>2</sub>O

b. Tidal Volume ..... 

--	--	--	--

 mL

c. PEEP ..... 

--	--

 cm H<sub>2</sub>O

d. FiO<sub>2</sub> ..... 

--	--	--

 %

D. Arterial Blood Gas obtained? ..... Yes  No

If Yes,

1. Arterial pH ..... 

--

 . 

--	--

2. PaCO<sub>2</sub> ..... 

--	--

 mmHg

3. PaO<sub>2</sub> ..... 

--	--	--

 mmHg

4. FiO<sub>2</sub> (percent) ..... 

--	--	--

 %

**Instructions for Form 6—Baseline Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials.**

**E. Hemodynamic Monitoring**

1. Mark 'yes' if a CVP catheter is being used; mark 'no' otherwise.
2. Mark 'yes' if a pulmonary artery catheter is being used; mark 'no' otherwise.
3. Enter the CVP value in mmHg if a CVP catheter or pulmonary artery catheter is being used. Mark the 'N/A' box if the data is not available.
4. Enter the pulmonary artery pressure as systolic/diastolic pressure in mmHg if a pulmonary artery catheter is being used. Mark the 'N/A' box if the data is not available.
5. Enter the value for pulmonary capillary occlusion pressure ("wedge" pressure) in mm Hg if a pulmonary artery catheter is being used. Mark the 'N/A' box if there was no reading obtained for pulmonary capillary occlusion pressure.

**F. Glasgow Coma Score**

1. Mark 'yes' if the patient is on sedation; mark 'no' otherwise.
2. Check the one box that indicates the best eye response.
3. Check the one box that indicates the best motor response.
4. If the patient is non-intubated, mark the one box under column (a) that indicates the best verbal response; **OR** if the patient is intubated, then mark the one box under column (b) that indicates the best verbal response.

**G. Hematology (Note: These should all be the most recent values obtained within 24 hours before starting on study treatment). For each item for which no value is available, check the N/A box.**

1. Enter the hemoglobin value in g/dL.
2. Enter the hematocrit (percent).
3. Enter the platelet count.
4. Enter the white blood cell count.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 06 - BASELINE SCORES AND LABORATORY VALUES

Hospital No.

--	--	--

Patient ID

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Patient Initials

--	--	--

E. Hemodynamic Monitoring

1. CVP catheter? ..... Yes  No

2. Pulmonary artery catheter? ..... Yes  No

3. CVP ..... 

--	--

 mmHg  N/A\*

4. Pulmonary artery pressure (systolic/diastolic) ..... 

--	--	--

 / 

--	--

 mmHg  N/A\*

5. Pulmonary capillary occlusion pressure ..... 

--	--

 mmHg  N/A\*

F. Glasgow Coma Score

1. Patient is on sedation? ..... Yes  No

2. Best Eye Response (check one)

- |                                              |                                                        |
|----------------------------------------------|--------------------------------------------------------|
| <input type="checkbox"/> No eye opening      | <input type="checkbox"/> Eye opening to verbal command |
| <input type="checkbox"/> Eye opening to pain | <input type="checkbox"/> Eyes open spontaneously       |

3. Best Motor Response (check one)

- |                                            |                                               |
|--------------------------------------------|-----------------------------------------------|
| <input type="checkbox"/> No motor response | <input type="checkbox"/> Withdrawal from pain |
| <input type="checkbox"/> Extension to pain | <input type="checkbox"/> Localizes pain       |
| <input type="checkbox"/> Flexion to pain   | <input type="checkbox"/> Obeys commands       |

4. Best Verbal Response (check one)

a. Non-Intubated

- No verbal response
- Incomprehensible sounds
- Inappropriate words
- Converses/Confused
- Converses/Orientated

b. Intubated

- Generally unresponsive
- Questionable ability to talk
- Seems able to talk

G. Hematology (Most recent values within 24 hours before start of study treatment.)

1. Hemoglobin ..... 

--	--

 . 

--

 g/dL  N/A\*

2. Hematocrit ..... 

--	--

 . 

--

 %  N/A\*

3. Platelet Count ..... 

--

 , 

--	--	--

 , 000 cells/mm<sup>3</sup>  N/A\*

4. White Blood Cell Count ..... 

--	--	--

 , 

--

 00 cells/mm<sup>3</sup>  N/A\*

**Instructions for Form 6 – Baseline Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials.**

**H. Coagulation – For each item for which no value is available, check the N/A box.**

1. Enter the INR value.
2. Enter the partial thromboplastin time in seconds.
3. Enter the upper limit of normal range of partial thromboplastin time in seconds.
4. Mark 'yes' if the patient is having active bleeding; mark 'no' otherwise.  
Active bleeding is defined as gastrointestinal, pulmonary, upper respiratory (including epistaxis), or retroperitoneal bleeding, bleeding from surgical sites, or other blood loss resulting in a need for transfusion or a decrease in hemoglobin concentration of > 1 g/dL/24 hours.

**I. Renal Function (Note: These should be the most recent values obtained prior to completing this form)**

1. Urine collection should normally be for 24 hours. Enter the **daily** urine volume in mL per total number of hours and enter the total number of hours.
2. Enter the serum creatinine in mg/dL. Enter the date on which this value was obtained.
3. Enter the value of BUN at admission in mg/dL.
4. Enter the value of the most recent BUN in mg/dL. Enter the date on which this value was obtained.

**J. Chemistry (Note: These should be the most recent values obtained prior to completing this form). For each item for which you have a value, enter the date that it was obtained as mm/dd/yy. For each item for which there is no value, check the N/A box.**

1. Enter the total bilirubin value in mg/dL.
2. Enter the SGOT (AST) in U/L.
3. Enter the SGPT (ALT) in U/L.
4. Enter the alkaline phosphatase value in U/L.
5. Enter the albumin value in g/dL.
  - a. enter the lower limit of normal for albumin in g/dL.
6. Enter the total cholesterol value in mg/dL.
7. Enter the serum sodium value in mEq/L.
8. Enter the serum potassium value in mEq/L.
9. Enter the total CO<sub>2</sub> (serum HCO<sub>3</sub>) value in mEq/L.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 06 - BASELINE SCORES AND LABORATORY VALUES

Hospital No.

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Patient ID

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Patient Initials

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H. Coagulation

- 1. INR ..... 







 . 



 N/A\*
- 2. Partial thromboplastin time (PTT) ..... 







 . 



 sec  N/A\*
- 3. Upper limit of normal PTT ..... 







 . 



 sec  N/A\*
- 4. Is patient having active bleeding (see Ops manual)? ..... Yes  No

I. Renal Function (Most recent values obtained prior to completing form)

- 1. Daily urine volume ..... 















 mL per 







 hours
- 2. Serum creatinine ..... 







 . 



 mg/dL 



 / 



 / 



 Date Obtained
- 3. BUN at admission ..... 











 mg/dL
- 4. Most recent BUN ..... 











 mg/dL 



 / 



 / 



 Date Obtained

J. Chemistry (Most recent values obtained prior to completing form)

- |                                                                                                                                                                                                                                                                                                                                                                                       | Date Obtained (mm/dd/yy)                                                                                                                                                                                                                                           |                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| 1. Total bilirubin ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> mg/dL                                                                                       | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | N/A*<br><input type="checkbox"/> |
| 2. SGOT (AST) ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> U/L           | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |
| 3. SGPT (ALT) ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> U/L           | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |
| 4. Alkaline phosphatase ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> U/L | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |
| 5. Albumin ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> g/dL                                                                                                                                                                                     | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |
| a. Lower limit of normal <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> g/dL                                                                                                                                                                             |                                                                                                                                                                                                                                                                    |                                  |
| 6. Total cholesterol ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> mg/dL  | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |
| 7. Serum sodium ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> mEq/L                                                                                            | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |
| 8. Serum potassium ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> mEq/L                                                                                                                                                                            | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |
| 9. Total CO <sub>2</sub> ..... <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> . <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> mEq/L                                                                                 | <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> / <table border="1" style="display: inline-table; width: 20px; height: 20px;"></table> | <input type="checkbox"/>         |

**Instructions for Form 6 – Baseline Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials.**

**J. Chemistry – continued (Note: These should be the most recent values obtained prior to completing this form). For each item for which you have a value, enter the date that it was obtained as mm/dd/yy. For each item for which there is no value, check the N/A box.**

10. Enter the serum calcium in mg/dL and the date it was obtained. Mark the 'N/A' box if it is not available.
11. Enter the ionized calcium value and the date it was obtained. Mark the 'N/A' box if it is not available. If a value is entered,
  - a. check the one box that indicates the units in which the ionized calcium was obtained.
12. Enter the serum phosphate value in mg/dL and the date it was obtained. Mark the 'N/A' box if it is not available.
13. Enter the magnesium value in mg/L and the date it was obtained. Mark the 'N/A' box if it is not available.

**K. Pressors for 1 hour or more (check all pressors that have been used for 1 hour or more).  
**NOTE: The dose of pressor recorded should be the maximal dose utilized for a period of at least 1 hour during the 24-hour period prior to enrollment in the study.****

1. Mark 'yes' if epinephrine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
2. Mark 'yes' if norepinephrine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
3. Mark 'yes' if phenylephrine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
4. Mark 'yes' if dopamine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
5. Mark 'yes' if dobutamine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
6. Mark 'yes' if vasopressin has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in units/hour.
7. Mark 'yes' if another pressor, other than 1 through 6 above, has been used for more than 1 hour; mark 'no' if otherwise. If 'yes', enter the dose and write in the name of the pressor that was used in the box provided.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 06 - BASELINE SCORES AND LABORATORY VALUES

Hospital No.

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Patient ID

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Patient Initials

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J. Chemistry (continued)

10. Serum calcium ----- 

--	--

 . 

--

 mg/dL

Date Obtained (mm/dd/yy)  

--	--

 / 

--	--

 / 

--	--

N/A\*

11. Ionized calcium ----- 

--

 . 

--	--

--	--

 / 

--	--

 / 

--	--

a. Measurement obtained in (check one):

mEq/L     mmol/L

12. Serum PO<sub>4</sub> ----- 

--	--

 . 

--

 mg/dL

--	--

 / 

--	--

 / 

--	--

13 Magnesium ----- 

--

 . 

--

 mg/dL

--	--

 / 

--	--

 / 

--	--

K. Pressors for 1 hour or more

	Yes	No	Dose					
1. Epinephrine (mcg/kg/min) -----	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>					
2. Norepinephrine (mcg/kg/min) -----	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>					
3. Phenylephrine (mcg/kg/min) -----	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>					
4. Dopamine (mcg/kg/min) -----	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td></tr></table>					
5. Dobutamine (mcg/kg/min) -----	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td></tr></table>					
6. Vasopressin (units/hr) -----	<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td></tr></table>					
7. Other, ----- specify <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 500px; height: 30px;"></td></tr></table>		<input type="checkbox"/>	<input type="checkbox"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>				

**Instructions for Form 6 – Baseline Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials.**

**L. Hemodialysis or 24 or fewer hours of CRRT prior to randomization.**

**Mark ‘yes’ if the patient had either hemodialysis or < 24 hours of CRRT prior to randomization; mark ‘no’ otherwise. If ‘yes’ is marked, complete the following 6 items with data values obtained prior to that dialysis treatment or CRRT and complete Form 9 for pre-study treatment dialysis/CRRT.**

1. Mark ‘yes’ if the patient was intubated or on mechanical ventilation before that dialysis treatment or initiation of CRRT; mark ‘no’ otherwise.
2. Enter the platelet count. Enter date this platelet count was obtained as mm/dd/yy. Mark the ‘N/A’ box if it is not available.
3. Enter the leukocyte count. Enter date this leukocyte count was obtained as mm/dd/yy. Mark the ‘N/A’ box if it is not available.
4. Enter the bilirubin value as mg/dL. Enter date this bilirubin was obtained as mm/dd/yy. Mark the ‘N/A’ box if it is not available.
5. Mark ‘yes’ if there was bleeding diathesis (active bleeding or coagulopathy); mark ‘no’ otherwise.
6. Enter the serum creatinine value as mg/dL. Enter date this serum creatinine was obtained as mm/dd/yy. Mark the ‘N/A’ box if it is not available.
7. Enter the BUN value as mg/dL. Enter date this BUN was obtained as mm/dd/yy. Mark the ‘N/A’ box if it is not available.

**M. Glucose Management**

1. Mark the ‘yes’ box if the patient is on continuous insulin infusion; otherwise mark the ‘no’ box.
2. Enter the value for the blood glucose concentration that was obtained closest to 8am in mg/dL.

**N. Glucocorticoid Therapy**

1. Mark the ‘yes’ box if the patient is receiving glucocorticoids; otherwise mark the ‘no’ box. NOTE: if ‘yes’, enter the dose in hydrocortisone equivalents (see ops manual). Check one.

**O. Gastrointestinal Complications at the time of initiation of RRT**

1. Mark the ‘yes’ box if, at the time of initiation of RRT, the patient had cholecystitis with perforation; otherwise mark the ‘no’ box.
2. Mark the ‘yes’ box, if at the time of initiation of RRT, the patient had active GI bleeding requiring > 2units of blood over 24 hours; otherwise mark the ‘no’ Box.
3. Mark the ‘yes’ box, if at the time of initiation of RRT, the patient had necrotizing enterocolitis; otherwise mark the ‘no’ box.
4. Mark the ‘yes’ box if, at the time of initiation of RRT, the patient had necrotizing pancreatitis; otherwise mark the ‘no’ box.

Enter the initials of the staff member completing this form.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 06 - BASELINE SCORES AND LABORATORY VALUES

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

L. Did patient have hemodialysis or  $\leq$  24 hrs of CRRT prior to randomization? ----- Yes  No

If yes, enter the following data with values obtained before that dialysis or CRRT prior to randomization and complete Form 09.

1. Patient was intubated or on mechanical ventilation ----- Yes  No

		Date Obtained (mm/dd/yy)	
2. Platelet count -----	[ ] , [ ][ ][ ] ,000 cells/mm	[ ][ ] / [ ][ ] / [ ][ ]	N/A* <input type="checkbox"/>
3. Leukocytes -----	[ ][ ][ ] , [ ] 00 cells/mm <sup>3</sup>	[ ][ ] / [ ][ ] / [ ][ ]	<input type="checkbox"/>
4. Bilirubin -----	[ ][ ] . [ ] mg/dL	[ ][ ] / [ ][ ] / [ ][ ]	<input type="checkbox"/>
5. Bleeding diathesis -----	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6. Serum creatinine -----	[ ][ ] . [ ] mg/dL	[ ][ ] / [ ][ ] / [ ][ ]	<input type="checkbox"/>
7. BUN -----	[ ][ ][ ] . [ ] mg/dL	[ ][ ] / [ ][ ] / [ ][ ]	<input type="checkbox"/>

M. Glucose Management

1. Is patient on a continuous insulin infusion? ----- Yes  No

2. Blood glucose concentration obtained closest to 8am. [ ] , [ ][ ][ ] mg/dL

N. Glucocorticoid Therapy

1. Is patient receiving glucocorticoids? ----- Yes  No   
(includes dexamethasone, hydrocortisone, prednisolone, methylprednisolone, and prednisone)

If yes, a. Dose in hydrocortisone equivalents (see Ops manual). Check one.

- <30mg/day
- 30-100mg/day
- >100mg-300mg/day
- >300mg/day

O. Gastrointestinal Complications at the Time of Initiation of RRT

- 1. Cholecystitis with perforation ----- Yes  No
- 2. GI bleeding requiring >2 units of blood over 24 hours ----- Yes  No
- 3. Necrotizing enterocolitis ----- Yes  No
- 4. Necrotizing pancreatitis ----- Yes  No

Staff Initials

[ ][ ][ ]

**H. Instructions for Form 7 – Study Day Scores and Laboratory Values**

Enter Hospital Number, Patient ID, Patient Initials, and the Study Day Date.

**When to complete this form:** This form should be completed for each of the first 14 days during which the patient is in the study and is on the study protocol therapy, and also on study days 21 and 28, if the patient is still on the study protocol therapy at those times.

**NOTE:** Day 1 is the day the patient was randomized into the study. Study day 7 is the 7<sup>th</sup> day the patient is in the study; study day 14 is the 14<sup>th</sup> day the patient is in the study; etc., always remembering that Day 1 is the day the patient was randomized into the study.

**NOTE:** Unless otherwise indicated, the rules for the timing of the data are: (1) For everything other than the Glasgow Coma Score, the value used should be the most abnormal for the 24-hour period. (2) For the Glasgow Coma Score, use the values that are the best for the 24-hour period.

- A. Indicate on which study day this data was obtained. The possible values are 01, 02, 03, ..., 14, 21, or 28, where day 01 is the day the patient was randomized into the study.
- B. Vital Signs (Data should be collected timed to the lowest blood pressure recorded.) **NOTE: It is important to ensure that the data represents the patient's true physiological state and not an artifact of monitoring.**
  - 1. Enter the patient's temperature (oral, rectal, tympanic, or core, but **not** cutaneous/axillary).
    - a. Mark the box that indicates the scale on which the temperature was read. Mark the 'Celsius' box if the temperature reading is in degrees Celsius; mark the 'Fahrenheit' box if the temperature reading is in degrees Fahrenheit.
  - 2. Enter the heart rate in beats per minute.
  - 3. Enter the respiratory rate in breaths per minute.

**NOTE:** For items 4 and 5 below, if the patient is being monitored with both an arterial line and non-invasive BP monitoring, use the arterial line as long as the value is clinically reliable and does not reflect dampening due to catheter artifact. If the arterial line value is dampened, then use the non-invasive BP.

- 4. Enter the blood pressure as systolic/diastolic in mmHg.
- 5. Enter the mean arterial pressure in mmHg as read from a monitoring system. Mark the 'N/A' box if this reading is available.
- 6. Enter SaO<sub>2</sub> as percent.
- C. **Fluid Intake and Output**
  - 1. Enter the 24-hour fluid intake in mL.
  - 2. Enter the 24-hour fluid output in mL, not including ultrafiltrate on RRT.
  - 3. Enter duration, in hours, of intake and output record if less than 24 hours.
- D. **Mark 'yes' if the patient is intubated or if the patient has a tracheostomy; mark 'no' otherwise. Base this answer on the patient's status at 8am.**
- E. **Mark 'yes' if the patient is on mechanical ventilation; mark 'no' otherwise. Base this answer on the patient's status at 8am.**

If the patient is on mechanical ventilation,

  - 1. Specify if patient is receiving invasive (intubated) mechanical ventilation or non-invasive (not intubated; e.g., BiPAP) mechanical ventilation.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 07 - STUDY DAY SCORES AND LABORATORY VALUES

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

Study Day Date (mm/dd/yy)

[ ][ ] / [ ][ ] / [ ][ ]

A. Study Day (day 01-14, 21, or 28) ----- [ ][ ]

B. Vital Signs

1. Temperature (in degrees C or F) ----- [ ][ ][ ] . [ ] Degrees

a. Scale used (check one)  Celsius  Fahrenheit

2. Heart Rate ----- [ ][ ][ ] beats/min

3. Respiratory Rate ----- [ ][ ] breaths/min

4. Blood Pressure (systolic/diastolic) ----- [ ][ ][ ] / [ ][ ][ ] mmHg

5. Mean Arterial Pressure as read from monitoring system ----- [ ][ ][ ] mmHg  N/A\*

6. Transcutaneous Hemoglobin Oxygen Saturation (SaO<sub>2</sub>) ----- [ ][ ][ ] %

C. Fluid Intake and Output

1. 24-hour intake in mL ----- [ ][ ][ ][ ][ ] mL

2. 24-hour output in mL ----- [ ][ ][ ][ ][ ] mL

3. Duration of intake and output record if < 24 hours ----- [ ][ ] hours

D. Patient intubated or has tracheostomy? ----- Yes  No

E. Patient on mechanical ventilation? ----- Yes  No

If Yes,

1. Specify (check one):

Invasive mechanical ventilation (intubated)

Non-invasive mechanical ventilation (non-intubated)

\*N/A means Not Available

**Instructions for Form 7 – Study Day Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials, and the Study Day Date.**

**F. Arterial Blood Gas – Mark ‘yes’ if arterial blood gas was obtained; mark ‘no’ otherwise. If ‘yes’, fill in the 4 items below. NOTE: If more than one blood gas has been obtained, enter the value of the blood gas that gives the lowest PaO<sub>2</sub>/FiO<sub>2</sub> ratio.**

1. Enter the value for arterial pH.
2. Enter the value for PaCO<sub>2</sub> in mmHg.
3. Enter the value for PaO<sub>2</sub> in mmHg.
4. Enter the value for FiO<sub>2</sub> as a percent.

**G. Hemodynamic Monitoring**

1. Mark ‘yes’ if a CVP catheter is being used; mark ‘no’ otherwise.
2. Mark ‘yes’ if a pulmonary artery catheter is being used; mark ‘no’ otherwise.
3. Enter the CVP value in mmHg if a CVP catheter or pulmonary artery catheter is being used. Mark the ‘N/A’ box if the value is not available.
4. Enter the pulmonary artery pressure as systolic/diastolic pressure in mmHg if a pulmonary artery catheter is being used. Mark the ‘N/A’ box if this value is not available.
5. Enter the value for pulmonary capillary occlusion pressure (“wedge” pressure) in mmHg if a pulmonary artery catheter is being used. Mark the ‘N/A’ box if this value was not obtained.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 07 - STUDY DAY SCORES AND LABORATORY VALUES

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

Study Day Date (mm/dd/yy)

[ ][ ] / [ ][ ] / [ ][ ]

F. Arterial Blood Gas Obtained? ..... Yes  No

If obtained,

1. Arterial pH ..... [ ] . [ ][ ]

2. PaCO<sub>2</sub> ..... [ ][ ] mmHg

3. PaO<sub>2</sub> ..... [ ][ ][ ] mmHg

4. FiO<sub>2</sub> (percent) ..... [ ][ ][ ] %

G. Hemodynamic Monitoring

1. CVP catheter? ..... Yes  No

2. Pulmonary artery catheter? ..... Yes  No

3. CVP ..... [ ][ ] mmHg  N/A\*

4. Pulmonary artery pressure (systolic/diastolic) [ ][ ][ ] / [ ][ ] mmHg  N/A\*

5. Pulmonary capillary occlusion pressure ..... [ ][ ] mmHg  N/A\*

\*N/A means Not Available

**Instructions for Form 7 – Study Day Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials, and the Study Day Date.**

**H. Glasgow Coma Score**

1. Mark 'yes' if the patient is on sedation; mark 'no' otherwise.
2. Check the one box that indicates the best eye response.
3. Check the one box that indicates the best motor response.
4. a. If the patient was not intubated, then check the one box beneath column (a) that indicates the best verbal response.  
b. If the patient was intubated, then check the one box beneath column (b) that indicates the best verbal response.

**I. Hematology/Coagulation**

1. Enter the value for hemoglobin in g/dL. Check the 'N/A' box if the value is not available.
2. Enter the white blood cell count in cells/mm<sup>3</sup>. Check the 'N/A' box if the value is not available.
3. Enter the platelet count. If more than one platelet count was obtained for the day, enter the lowest value. Check the 'N/A' box if the platelet count is not available.
4. Mark 'yes' if the patient is having active bleeding; mark 'no' otherwise. Active bleeding is defined as gastrointestinal, pulmonary, upper respiratory (including epistaxis), or retroperitoneal bleeding, bleeding from surgical sites or other blood loss resulting in a need for transfusion or a decrease in hemoglobin concentration of > 1 g/dL/24 hours.

**J. Renal Function**

1. Urine collection should normally be for 24 hours. Enter the **daily** urine volume in mL per total number of hours and enter the total number of hours.
2. Enter the serum creatinine in mg/dL. Check the 'N/A' box if the serum creatinine is not available.
3. Enter the value of the most recent BUN in mg/dL. Check the 'N/A' box if the BUN is not available.
4. Check 'yes' if the urine volume is greater than 30 mL per hour and if the 6-hour urine collection was performed; check 'no' otherwise.

If 'yes':

Enter the value of the urine volume from the 6-hour urine collection and the value of the urine creatinine from the 6-hour urine collection.

**Note: The 6-hour timed urine collection is to be performed to monitor creatinine clearance in all patients with urine volume > 30 mL/hour (720 mL/day) three-times per week (see Ops Manual Section VIII.E). Collections are to be performed on non-dialysis days in patients randomized to the conventional therapy arm and on alternating dialysis treatment days for patients randomized to the intensive therapy arm and for all patients on CVVHDF. The urine collection should be timed so that the daily lab-work is obtained at the approximate mid-point of the urine collection.**

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 07 - STUDY DAY SCORES AND LABORATORY VALUES

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

--	--	--

Study Day Date (mm/dd/yy)

--	--	--	--	--	--	--

H. Glasgow Coma Score

1. Patient is on sedation?..... Yes  No

2. Best Eye Response (check one)

- |                                              |                                                        |
|----------------------------------------------|--------------------------------------------------------|
| <input type="checkbox"/> No eye opening      | <input type="checkbox"/> Eye opening to verbal command |
| <input type="checkbox"/> Eye opening to pain | <input type="checkbox"/> Eyes open spontaneously       |

3. Best Motor Response (check one)

- |                                            |                                               |
|--------------------------------------------|-----------------------------------------------|
| <input type="checkbox"/> No motor response | <input type="checkbox"/> Withdrawal from pain |
| <input type="checkbox"/> Extension to pain | <input type="checkbox"/> Localizes pain       |
| <input type="checkbox"/> Flexion to pain   | <input type="checkbox"/> Obeys commands       |

4. Best Verbal Response (check one)

a. Non-Intubated

- No verbal response
- Incomprehensible sounds
- Inappropriate words
- Converses/Confused
- Converses/Orientated

b. Intubated

- Generally unresponsive
- Questionable ability to talk
- Seems able to talk

I. Hematology/Coagulation

1. Hemoglobin..... 

--	--

 . 

--

 g/dL  N/A\*
2. White blood cell count..... 

--	--	--

 , 

--

 00 cells/mm<sup>3</sup>  N/A\*
3. Platelet Count..... 

--

 , 

--	--	--

 , 000 cells/mm<sup>3</sup>  N/A\*
4. Is patient having active bleeding?..... Yes  No

J. Renal Function

1. Daily urine volume..... 

--	--	--	--	--

 mL per 

--	--

 hours
2. Serum creatinine..... 

--	--

 . 

--

 mg/dL  N/A\*
3. BUN..... 

--	--	--

 mg/dL  N/A\*
4. Was a 6-hour urine collection performed? (See Ops Manual)..... Yes  No
- If Yes,
- a. Urine volume..... 

--	--	--	--

 mL
- b. Urine creatinine..... 

--	--	--

 . 

--

 mg/dL

**Instructions for Form 7 – Study Day Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials, and the Study Day Date.**

**K. Chemistry**

1. Enter the total bilirubin value in mg/dL. If more than one value is obtained for the day, enter the highest value.
2. Enter the albumin value in g/dL.
3. Enter the total cholesterol value in mg/dL.
4. Enter the serum sodium value in mEq/L.
5. Enter the serum potassium value in mEq/L.
6. Enter the total CO<sub>2</sub> (serum HCO<sub>3</sub>) value in mEq/L.
7. Enter the serum calcium in mg/dL. Mark the 'N/A' box if it is not available.
8. Enter the ionized calcium value. Mark the 'N/A' box if it is not available. If a value is entered,
  - a. check the one box that indicates the units in which the ionized calcium was obtained.
9. Enter the serum phosphate value in mg/dL. Mark the 'N/A' box if it is not available.
10. Enter the magnesium value in mg/L. Mark the 'N/A' box if it is not available.

**L. Maximal pressor used for greater than one hour (check all pressors that have been used for 1 hour or more). NOTE: The dose of pressor recorded should be the maximal dose utilized for a period of at least 1 hour during the 24-hour period.**

1. Mark 'yes' if epinephrine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
2. Mark 'yes' if norepinephrine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
3. Mark 'yes' if phenylephrine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
4. Mark 'yes' if dopamine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
5. Mark 'yes' if dobutamine has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in mcg/kg/min.
6. Mark 'yes' if vasopressin has been used for 1 hour or more; mark 'no' otherwise. If 'yes', enter the dose in units/hour.
7. Mark 'yes' if a pressor other than 1 through 6 above has been used for more than 1 hour; mark 'no' if otherwise. If 'yes', enter the dose and write in the name of the pressor that was used in the box provided.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 07 - STUDY DAY SCORES AND LABORATORY VALUES

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

--	--	--

Study Day Date (mm/dd/yy)

--	--	--	--	--	--	--

K. Chemistry

- |                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--------------------------|----------------------------------|--------------------------|
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 1. Total bilirubin .....                                                                               | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> mg/dL |  |  |  |  |                          | N/A*<br><input type="checkbox"/> |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 2. Albumin .....                                                                                       | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> g/dL                                              |  |  |  |  | <input type="checkbox"/> |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 3. Total cholesterol .....                                                                             | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> mg/dL                          |  |  |  |  |                          |                                  | <input type="checkbox"/> |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 4. Serum sodium .....                                                                                  | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> mEq/L                                                                      |  |  |  |  |                          | <input type="checkbox"/>         |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 5. Serum potassium .....                                                                               | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> mEq/L                                             |  |  |  |  | <input type="checkbox"/> |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 6. Total CO <sub>2</sub> .....                                                                         | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> mEq/L |  |  |  |  |                          | <input type="checkbox"/>         |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 7. Serum Calcium .....                                                                                 | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> mg/dL |  |  |  |  |                          | <input type="checkbox"/>         |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 8. Ionized calcium .....                                                                               | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>       |  |  |  |  |                          | <input type="checkbox"/>         |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| a. Measurement obtained in (check one): <input type="checkbox"/> mEq/L <input type="checkbox"/> mmol/L |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 9. Serum PO <sub>4</sub> .....                                                                         | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> mg/dL |  |  |  |  |                          | <input type="checkbox"/>         |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
| 10. Magnesium .....                                                                                    | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> mg/dL |  |  |  |  |                          | <input type="checkbox"/>         |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |
|                                                                                                        |                                                                                                                                                                                                                                                                                   |  |  |  |  |                          |                                  |                          |

L. Pressors for 1 hour or more (See Operations Manual for timing of data collection.)

- |                                      |                          |                          | Dose                                                                                                                                                                                                                                                                                                                    |  |  |  |  |  |
|--------------------------------------|--------------------------|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
|                                      | Yes                      | No                       |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| 1. Epinephrine (mcg/kg/min) .....    | <input type="checkbox"/> | <input type="checkbox"/> | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>                                             |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| 2. Norepinephrine (mcg/kg/min) ..... | <input type="checkbox"/> | <input type="checkbox"/> | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>                                             |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| 3. Phenylephrine (mcg/kg/min) .....  | <input type="checkbox"/> | <input type="checkbox"/> | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>                                             |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| 4. Dopamine (mcg/kg/min) .....       | <input type="checkbox"/> | <input type="checkbox"/> | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table>                                             |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| 5. Dobutamine (mcg/kg/min) .....     | <input type="checkbox"/> | <input type="checkbox"/> | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table>                                             |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| 6. Vasopressin (units/hr) .....      | <input type="checkbox"/> | <input type="checkbox"/> | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td></tr></table>                                             |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| 7. Other, .....                      | <input type="checkbox"/> | <input type="checkbox"/> | <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
|                                      |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |
| specify                              |                          |                          |                                                                                                                                                                                                                                                                                                                         |  |  |  |  |  |

**Instructions for Form 7 – Study Day Scores and Laboratory Values**

**Enter Hospital Number, Patient ID, Patient Initials, and the Study Day Date.**

**M. Nutrition Management**

1. Mark ‘yes’ if the patient is NPO; mark ‘no’ otherwise.
2. Mark ‘yes’ if oral supplements are being used; mark ‘no’ otherwise.
  - a. For Formulation 1:
    - i. Enter the code for the type of oral supplement being used (see the coding section of the Ops Manual).
    - ii. Enter the volume of undiluted oral supplement actually administered (mL/day).
  - b. For Formulation 2 (if the formulation changed during the day):
    - i. Enter the code for the type of oral supplement being used (see the coding section of the Ops Manual).
    - ii. Enter the volume of undiluted oral supplement actually administered (mL/day).
3. Mark ‘yes’ if tube feeding is being used; mark ‘no’ otherwise.
  - a. For Formulation 1:
    - i. Enter the code for the tube feeding formulation (see the coding section of the Ops Manual).
    - ii. Enter volume of undiluted tube feed actually administered (mL/day).
  - b. For Formulation 2 (if the formulation changed during the day):
    - i. Enter the code for the tube feeding formulation (see the coding section of the Ops Manual).
    - ii. Enter volume of undiluted tube feed actually administered (mL/day).
4. Mark ‘yes’ if TPN is prescribed; mark ‘no’ otherwise.
  - a. Enter the number of calories per day administered.
  - b. Enter the number of grams of protein per day administered.
  - c. Enter the number of grams of lipid per day administered.

**N. Glucose Management**

1. Mark the ‘yes’ box if the patient is on continuous insulin infusion; otherwise mark the ‘no’ box. NOTE: Answer ‘yes’ if the patient was on continuous insulin infusion for glucose management **for at least 4 hours** in the 24-hour period.
2. Enter the value for the blood glucose concentration that was obtained closest to 8am in mg/dL.

**O. Glucocorticoid Therapy**

1. Mark the ‘yes’ box if the patient is receiving glucocorticoids; otherwise mark the ‘no’ box. If yes,
  - a. check the one box that indicates the dose in hydrocortisone equivalents of the glucocorticoid that the patient is receiving (see table below).

	Relative Anti-inflammatory Potency*	Equivalent Doses (mg/day)		
		30	100	300
Hydrocortisone	1	30	100	300
Prednisone	4	7.5	25	75
Methylprednisolone	5	6	20	60
Dexamethasone	25	1.2	4	12

\* Adapted from Hardman JG and Limbird LE (editors.). Goodman and Gilman’s The Pharmacological Basis of Therapeutics, 9th Edition. New York: McGraw-Hill Health Professions Division. 1996; page 1466.

Enter the date that this form was completed as mm/dd/yy and enter the initials of the staff member completing this form.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 07 - STUDY DAY SCORES AND LABORATORY VALUES

Hospital No.  
[ ][ ][ ]

Patient ID  
[ ][ ][ ]

Patient Initials  
[ ][ ][ ]

Study Day Date (mm/dd/yy)  
[ ][ ] / [ ][ ] / [ ][ ]

M. Nutrition Management

1. NPO ----- Yes  No

2. Oral Supplements ----- Yes  No

a. Formulation 1

i. Type of Supplement (see Ops Manual for codes) ----- [ ][ ][ ]

ii. Number of mL administered per day ----- [ ][ ][ ][ ] mL

b. Formulation 2 (if formulation changed during the day)

i. Type of Supplement (see Ops Manual for codes) ----- [ ][ ][ ]

ii. Number of mL administered per day ----- [ ][ ][ ][ ] mL

3. Tube Feed ----- Yes  No

a. Formulation 1

i. Formulation (see Ops Manual for codes) ----- [ ][ ][ ]

ii. Number of mL administered per day ----- [ ][ ][ ][ ] mL

b. Formulation 2 (if formulation changed during the day)

i. Formulation (see Ops Manual for codes) ----- [ ][ ][ ]

ii. Number of mL administered per day ----- [ ][ ][ ][ ] mL

4. TPN ----- Yes  No

a. Calories/day ----- [ ][ ][ ][ ] Calories

b. Protein/day ----- [ ][ ][ ] grams

c. Lipids/day ----- [ ][ ][ ] grams

N. Glucose Management

1. Is patient on a continuous insulin infusion? ----- Yes  No

2. Blood glucose concentration obtained closest to 8:00am. [ ][ ], [ ][ ][ ][ ] mg/dL

O. Glucocorticoid Therapy

1. Is patient receiving glucocorticoids? ----- Yes  No   
(includes dexamethasone, hydrocortisone, prednisolone, methylprednisolone, prednisone)

a. If yes, dose in hydrocortisone equivalents (See Ops Manual). Check one.

- <30mg/day
- 30-100mg/day
- >100mg-300mg/day
- >300mg/day

Date of Form Completion (mm/dd/yy)

[ ][ ] / [ ][ ] / [ ][ ]

Staff Initials

[ ][ ][ ]

Page 1 of 1

**I. Instructions for Form 8 – Medications Form**

**Enter Hospital Number, Patient ID, Patient Initials, and the Date Form Completed.**

**When to complete this form: This form must be completed at most twice during the study. Complete Form 8 on study day 8 and study day 28. If the patient exits the study prior to day 8, then the form should be completed at study exit. If the patient exits the study between day 8 and day 28, the form should be completed on day 8 and at study exit. Remember that study day 1 is the day the patient was randomized into the study.**

**Note: Drugs are listed by generic name. For a detailed list that cross-references the trade and generic names, see the coding section of the Ops Manual. If you have any questions on a drug name or if the drug should affect renal function, please contact the CSPCRPCC pharmacist listed in the study personnel listing.**

- A. Check the box labeled ‘1-7’ if the data on this form refers to study days 1 through 7; check the box labeled ‘8-28’ if the data on this form refers to study days 8 through 28. Check one box only.**
  
- B. Check each box for which the drug indicated was taken at any time during the period for which this form is being completed. The box should be checked even if the patient received only one dose of the medication. If the box labeled ‘other drugs which are thought to affect renal function’ is checked, please specify up to six such drugs in the text boxes provided.**

Enter the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 08 - MEDICATIONS FORM

Hospital No.

Patient ID

Patient Initials

Date Form Completed (mm/dd/yy)

/  /

NOTES: 1. This form is to be completed at most twice during the study: Once for the time period covering from randomization through day 7 post-randomization and the second time for the period covering days 8 through 28 post-randomization.

2. Drugs are listed by generic name. For a detailed list that cross references the trade and generic names of the drugs, see the Coding Section of the Ops Manual.

A. Form is being completed for Study Days (check one)..... 1-7  8-28

B. CHECK ALL THAT APPLY IF TAKEN AT ANY TIME DURING THE PERIOD FOR WHICH THIS FORM IS BEING COMPLETED.

- acetylcysteine (same as n-acetylcysteine, Mucomyst<sup>R</sup> or Mucosil<sup>R</sup>)
- activated drotrecogin alpha (same as drotrecogin alpha, Xigris<sup>R</sup>, or activated Protein C)
- aldosterone antagonists (such as spironolactone, Aldactone<sup>R</sup>, eplerenone<sup>R</sup>, I nspra )
- aminoglycoside antibiotics (such as amikacin, gentamicin, kanamycin, tobramycin)
- amphotericin B (not bladder irrigation; same as Amphocin<sup>R</sup> , Fungizone<sup>R</sup>, Amphotec<sup>R</sup>, Ablecet<sup>R</sup>, or AmBisome<sup>R</sup>)
- angiotensin converting enzyme inhibitors (such as captopril, enalapril, fosinopril, lisinopril)
- angiotensin receptor blockers (such as candesartan, losartan, valsartan)
- cyclosporin or cyclosporin A (same as Sandimmune<sup>R</sup> or Neoral<sup>R</sup>)
- diuretics (such as bumetanide, furosemide, torsemide, thiazides, metolazone, acetazolamide)
- erythropoietic agents (same as epoetin alfa, Epogen<sup>R</sup>, Procrit<sup>R</sup>, darbepoetin alfa, Aranesp<sup>R</sup>)
- fenoldopam (same as Corlopam<sup>R</sup>)
- NSAIDs/COX-2 inhibitors
- tacrolimus (same as Prograf<sup>R</sup>)
- x-ray contrast media (intra-venous or intra-arterial, not oral, not gadolinium)
- other drugs which are thought to affect renal function

Specify:

1.

4.

2.

5.

3.

6.

Staff Initials

**J. Instructions for Form 9 – Renal Replacement Therapy – Each Treatment**

Enter Hospital Number, Patient ID, Patient Initials, Treatment Date, and Treatment number this date (e.g., If question A.2. below is filled in with a study day number, then the first treatment on this study day date is 1, the second on this study day date is 2, etc. If question A.1. below is coded 00, then enter a zero in this box).

**When to complete this form:** This form should be completed for each of the study days (study day 1 up to study day 28) during which the patient is in the study and receives RRT. Note that ‘day 1’ refers to the day the patient was randomized into the study and ‘day 28’ refers to the 28<sup>th</sup> day the patient is in the study. In addition, if the patient received RRT prior to randomization, this form should be completed retrospectively for that one treatment.

**A. Indicate on which study day this data was obtained (Choose one only).**

1. Enter the value ‘00’ if the data is from **before** the patient was randomized (pre-randomization); otherwise leave blank.
2. Enter a value between 1 and 28 to indicate which study day this data is for, where day ‘01’ refers to the day the patient was randomized into the study, day ‘04’ refers to the 4<sup>th</sup> day the patient is in the study, day ‘10’ refers to the 10<sup>th</sup> day the patient is in the study, etc.. Enter leading zeros; e.g., enter 01 for study day 1. Leave blank if ‘00’ was entered in the boxes for item 1 above.

**B. Time of day the Renal Replacement Therapy was started – enter the value as military time; e.g., 8am will be 0800, noon will be 1200, and 8pm will be 2000.**

**Note: If the patient is continuing on continuous therapy from the previous day, enter the treatment start time for the ICU flow sheet for the day. If the data flow sheet used runs other than midnight to midnight, use the institution 24-hour cycle for each day of therapy.**

1. Check ‘Yes’ if patient is on continuous therapy, continued from the previous day; check ‘no’ otherwise.

**C. Selection of RRT Modality on each day is determined by that day’s Cardiovascular SOFA Score. Refer to figure VIII-1 on page VIII-2 for an algorithm to guide selection of therapy.**

1. Enter the Cardiovascular SOFA Score.
2. Indicate the type of RRT – check one box only and complete the appropriate section for that type of RRT, **and** complete section G for all types of RRT.

**D. Isolated Ultrafiltration**

1. Indication for isolated ultrafiltration.
  - a. Check ‘yes’ if there is severe edema; check ‘no’ otherwise. Severe is defined as edema with evidence of tissue compromise.
  - b. Check one box to indicate the clinical examination of the lungs.
  - c. Enter the CVP value in mmHg. Check the ‘N/A’ box if not available.
  - d. Enter the pulmonary artery pressure as systolic/diastolic pressure in mmHg. Check the ‘N/A’ box if not available.
  - e. Enter the pulmonary capillary occlusion pressure (“wedge” pressure) value in mmHg. Check the ‘N/A’ box if not available.
  - f. For oxygenation, enter the hemoglobin oxygenation saturation (SaO<sub>2</sub>), measured transcutaneously, in percent saturation or the arterial oxygenation (PaO<sub>2</sub>), measured by an arterial blood gas in mmHg. Provide the administered oxygen as either the percent oxygen administered (FiO<sub>2</sub>) (e.g., 0.40=40%) or as the oxygen flow rate in liters/minute, as appropriate.
2. Enter the duration of ultrafiltration in hours and minutes. If there are no minutes, please enter 00 in the minutes boxes. If there are no hours, please enter 00 in the hours boxes.
3. Enter the dialyzer code (see the coding section of the Ops Manual).
4. Enter the blood flow rate in mL/minute.
5. Enter the pre-treatment weight in kilograms. Check the ‘N/A’ box if value not available.
6. Enter the amount of net fluid removed in liters.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 09 - RENAL REPLACEMENT THERAPY - EACH TREATMENT

Treatment No.  
This Date

Hospital No.

Patient ID

Patient Initials

Treatment Date (mm/dd/yy)

A. Treatment Day (choose one only)

1.  Pre-randomization (code 00)

2.  Study Day (code 01, 02, 03, ..., 28)

B. Time of day RRT started (military)

 hours

1. If on continuous therapy, is it continued from previous day? -----  Yes  No

C. Selection of RRT Modality

1. Cardiovascular SOFA Score

2. Type of RRT (check one)

Hemodialysis (complete section E)

CVVHDF (complete section F)

SLED (complete section E)

Isolated Ultrafiltration (complete section D)

D. ISOLATED ULTRAFILTRATION

1. Indication for isolated ultrafiltration

a. Severe Edema -----  Yes  No

b. Lungs (check one) -----  Clear  Pulmonary Vascular Congestion

c. CVP -----  mmHg  N/A\*

d. Pulmonary Artery Pressure (systolic/diastolic) -----  /  mmHg  N/A\*

e. Pulmonary Capillary Occlusion Pressure -----  mmHg  N/A\*

f. Oxygenation ----- SaO<sub>2</sub>  % OR PaO<sub>2</sub>  mmHg

FiO<sub>2</sub>  % OR Oxygen flow rate  liters/min

2. Duration of ultrafiltration -----  hours  minutes

3. Dialyzer (see Ops manual for codes) -----  mL/min

4. Blood flow rate -----

5. Pre-treatment weight -----  kg  N/A\*

6. Fluid removal -----  L

**Instructions for Form 9 – Renal Replacement Therapy – Each Treatment**

**Enter Hospital Number, Patient ID, Patient Initials, the Treatment Date, and Treatment number this date.**

**E. Hemodialysis or SLED**

1. Dialyzer code (see coding section of Ops Manual).
2. Enter the actual duration of dialysis in hours and minutes. If there are no minutes, please enter 00 for minutes. If there are no hours please enter 00 for hours.
3. Enter the average achieved blood flow rate in mL/minute.
4. Enter the dialysate flow rate in mL/minute.
5. Enter the pre-treatment weight in kilograms.
6. Enter the **net** amount of fluid removed in liters.
7. If assessment of dialysis adequacy was performed, mark 'yes'; otherwise mark 'no'.

**NOTE: Pre- and post-dialysis BUNs must be collected and Kt/V calculated at least 3 times per week for the first 2 weeks the patient is on the study, and at least once per week for the remainder of the time the patient is on study as indicated in Table VIII-2.**

**If yes,**

- a. Enter the BUN value at the initiation of today's treatment as mg/dL.
  - b. Enter the BUN value at the termination of today's treatment as mg/dL.
  - c. Enter the value of spKt/V as per worksheet VIII-5.
8. Anticoagulation – Check the one box that indicates the anticoagulant. If 'other' is checked, please specify the agent used in the box provided.
  9. Check 'yes' if clotting of the extracorporeal circuit dialyzer during dialysis required replacement of the hemodialyzer; check 'no' otherwise.
  10. a. Enter the blood pressure taken at the initiation of the treatment (pre-dialysis BP) in mmHg.  
b. Enter the lowest blood pressure documented during treatment in mmHg.

**F. CVVHDF**

1. Enter the code for the hemodiafilter (see the coding section of the Ops Manual).
2. Enter the duration of the therapy in hours and minutes. If there are no minutes, enter 00 for minutes. If there are no hours, enter 00 for hours.
3. Enter prescribed blood flow rate in mL/minute.
4. Dialysate flow rate:
  - a. Enter the prescribed dialysate flow rate as mL/hour.
  - b. Enter the code for the dialysate used (see the coding section of the Ops Manual).
5. Replacement fluid administration rate:
  - a. Enter the prescribed replacement fluid administration rate as mL/hour.
  - b. Enter the code for the replacement fluid used (see the coding section of the Ops Manual).

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 09 - RENAL REPLACEMENT THERAPY - EACH TREATMENT

Treatment No.  
This Date

Hospital No.	Patient ID	Patient Initials	Treatment Date (mm/dd/yy)	Treatment No.	This Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>	<input type="text"/>

E. HEMODIALYSIS or SLED

- Dialyzer (see Ops Manual for codes) -----
- Actual duration of dialysis (hours and minutes) -----  hours  mins
- Blood flow rate (average achieved) -----  mL/min
- Dialysate flow rate -----  mL/min
- Pre-dialysis weight -----  kg  N/A\*
- Net fluid removal (based on ultrafiltration monitor and administered fluids) -----  L
- Assessment of dialysis adequacy performed? ----- Yes  No

NOTE: Pre- and Post-dialysis BUNs are to be collected and Kt/V calculated at least 3 times per week for first 2 weeks on study and at least once per week for the remainder of the time the patient is on the study therapy.

- If yes,
- BUN at initiation of today's treatment -----  mg/dL
  - BUN at termination of today's treatment -----  mg/dL
  - Calculated spKt/V -----  .
- Anticoagulation (choose one)  None  Heparin  Citrate  Other, specify
  - Clotting of extracorporeal circuit requiring hemodialyzer replacement? -----  Yes  No
  - a. Blood pressure at initiation of treatment -----  /  mmHg
  - b. Lowest documented blood pressure during treatment -----  /  mmHg

F. CVVHDF

- Hemodiafilter (see Ops Manual for codes) -----
- Actual duration of therapy (hours and minutes) -----  hours  mins
- Blood flow rate (prescribed) -----  mL/min
- Dialysate flow rate (prescribed) ----- a.  mL/hour  
b. Dialysate code  (see Ops Manual)
- Replacement fluid administration rate (prescribed) ----- a.  mL/hour  
b. Replacement Fluid Code  (see Ops Manual)

**Instructions for Form 9 – Renal Replacement Therapy – Each Treatment**

**Enter Hospital Number, Patient ID, Patient Initials, the Treatment Date, and Treatment number this date.**

**F. CVVDHF (cont'd)**

6. Enter the prescribed ultrafiltration rate as mL/hour.
7. Enter the actual 24-hour effluent volume in liters.
8. Anticoagulation – Check the one box that indicates the anticoagulant.  
If 'other' is checked, please specify the agent used in the box provided.
9. Check 'yes' if clotting of the extra corporeal circuit during dialysis required replacement of the hemodiafilter; check 'no' otherwise.
10. Enter the number of hemodiafilters used during this 24-hour treatment period.

**G. Complications of Therapy – For each of the complications listed below that occurred during this RRT session, please mark either the 'no' or the 'yes' box. If the 'yes' box is marked and the complication can be classified as a serious adverse event (SAE), then also mark the SAE box to the right of the 'yes' box. If the complication is both serious and treatment-related, please remember to fill out a Serious Adverse Event Form (Form 16) also.**

1. Anaphylactic reaction to dialyzer ("first-use" reaction).
2. Hypotension requiring initiation of pressor support during treatment.
3. Hypotension requiring discontinuation of therapy.
4. Hypotension requiring other intervention.
5. Air embolism.
6. Bleeding (e.g., due to system disconnection or dialyzer rupture).
7. New onset of serious arrhythmia requiring discontinuation of therapy (e.g., rapid supraventricular tachycardia with hypotension, ventricular tachycardia).
8. Iatrogenic fluid and/or electrolyte imbalances.
  - a. If yes, enter the code for the type of imbalance (see coding section of the Ops Manual).
9. Seizures.
10. Other – If 'yes' is marked, please specify what the complication is in the boxes provided.

**NOTE: If any complications have occurred that are both serious and treatment-related, please fill out a separate serious adverse event form (Form 16) for each one of them.**

Hypotension is a common and expected complication of renal replacement therapy, particularly in patients with underlying hemodynamic instability. Although the majority of episodes of hypotension associated with renal replacement therapy are likely to be transient and not life threatening, a substantial number may be severe enough to warrant reporting as Serious Adverse Events. Although the determination of whether a particular episode should be reported is **at the discretion of the site investigator**, the following criteria provide **general guidance** for when hypotension during study therapy should be reported as a Serious Adverse Event:

1. Hypotension requiring discontinuation of study treatment<sup>1</sup>;
2. Hypotension requiring initiation or significant escalation of vasopressor therapy<sup>2</sup>; or
3. Hypotension that results in an associated untoward event<sup>3</sup>

<sup>1</sup> For example, premature termination of an intermittent hemodialysis treatment, with or without conversion to CVVHDF or SLED would probably constitute an SAE.

<sup>2</sup> For example, a sustained increase in dopamine dose from 4 to 20 mcg/kg/min or the addition of norepinephrine to a maximal rate of dopamine infusion would probably constitute SAEs while an increase in dopamine infusion from 4 to 6 mcg/kg/min would probably not constitute an SAE.

<sup>3</sup> For example, an episode of hypotension that results in signs or symptoms of myocardial, cerebrovascular or mesenteric ischemia.

Enter the date on which the form was completed as mm/dd/yy and enter the initials of the staff member completing the form.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 09 - RENAL REPLACEMENT THERAPY - EACH TREATMENT

Treatment No.  
This Date

Hospital No.

Patient ID

Patient Initials

Treatment Date (mm/dd/yy)

F. CVVHDF (cont'd)

6. Ultrafiltration rate (prescribed) .....  mL/hour

7. 24-hour effluent volume (actual) .....  L

8. Anticoagulation (choose one)

- None
- Heparin
- Citrate
- Other, specify

9. Clotting of extracorporeal circuit requiring hemodiafilter replacement? .....  Yes  No

10. Number of hemodiafilters used during this 24-hour treatment period .....

If Yes,  
check if it  
is an SAE\*

G. COMPLICATIONS OF THERAPY (complete for all types of RRT)

No Yes

1. Anaphylactic reaction to dialyzer ("first-use" reaction) .....

2. Hypotension requiring initiation of pressor support during treatment .....

3. Hypotension requiring discontinuation of therapy .....

4. Hypotension requiring other intervention .....

5. Air embolism .....

6. Bleeding (e.g., due to system disconnection or dialyzer rupture) .....

7. New onset of serious arrhythmia requiring discontinuation of therapy (e.g., rapid supraventricular tachycardia with hypotension, ventricular tachycardia) .....

8. Iatrogenic fluid and/or electrolyte imbalances .....

a. If yes, type of imbalance (see OPs Manual)

9. Seizures .....

10. Other .....

Specify:

NOTE: \*IF ANY COMPLICATIONS HAVE OCCURRED THAT ARE BOTH SERIOUS AND TREATMENT-RELATED, PLEASE FILL OUT A SEPARATE SERIOUS ADVERSE EVENT FORM (Form 16) FOR EACH.

Date of Form Completion

Staff Initials

**K. Instructions for Form 10 – Discontinuation of Study Therapy**

Enter Hospital Number, Patient ID, Patient Initials, and date on which study therapy was discontinued.

**When to complete this form: This form must be completed for all patients enrolled in the study and should be completed ASAP after discontinuation of study therapy.**

**A. Indications for Discontinuation of Study Therapy – Choose only one of items 1 through 8 below.**

- 1. Recovery of Renal Function** – mark ‘yes’ if there was recovery of renal function; mark ‘no’ otherwise. If ‘yes’ is marked,
  - a. Mark ‘yes’ if there was an increase in urine volume; mark ‘no’ otherwise’. If ‘yes’ is marked, enter urine volume as mL/day.
  - b. Mark ‘yes’ if there was a spontaneous fall in serum creatinine; mark ‘no’ otherwise’. If ‘yes’ is marked,
    1. Enter value of the current serum creatinine as mg/dL and the date on which that value was obtained as mm/dd/yy.
    2. Enter the prior value of the serum creatinine in mg/dL and the date on which that value was obtained as mm/dd/yy.
  - c. Mark ‘yes’ if measured creatinine clearance by protocol specified urine collection is greater than 12mL/min; mark ‘no’ otherwise.
- 2. Withdrawal of life-support** – Check this box if this was the reason for discontinuation of study therapy.
- 3. Patient death** – Check this box if this was the reason for discontinuation of study therapy. If this box is checked, complete Form 13.
- 4. Patient withdrew or was withdrawn from the study** – Check this box if this was the reason for discontinuation of study therapy. If this box is checked, complete Form 13.
- 5. Patient was discharged from the hospital or transferred elsewhere on or before study day 28** – Check this box if this was the reason for discontinuation of the study therapy.
- 6. Site was terminated from study participation** – Check this box if this was the reason for discontinuation of the study therapy. If this box is checked, complete Form 13.
- 7. The DSMB (Data and Safety Monitoring Board) terminated the study** – Check this box if this was the reason for discontinuation of the study therapy. If this box is checked, complete Form 13.
- 8. Reached study day 28** – Check this box if patient remained on study RRT through day 28 and this was the reason for discontinuation of study therapy. If this box is checked, complete Form 11.
- 9. Other** – Check this box if the reason for discontinuation of the study therapy is not given in items 1 through 7 above. If this box is checked, specify the reason in the box provided.

**B. Mark ‘yes’ if initial consent obtained by a surrogate; mark ‘no’ otherwise. If ‘yes’, complete Form 2R (Re-consent Form Cover Sheet) if it has not been previously completed. If the patient has regained decision-making capacity, be sure to re-consent the patient with the informed re-consent form. Mail Form 2R and a copy of signed informed re-consent to WH CSPCC ASAP.**

Enter date on which form was completed as mm/dd/yy and enter initials of the staff member completing the form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 10-DISCONTINUATION OF STUDY THERAPY

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

Date Study Therapy Discontinued

[ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

NOTE: THIS FORM MUST BE COMPLETED FOR ALL SUBJECTS ENROLLED IN THE STUDY.

A. Indications for Discontinuation of Study Therapy (check one of items 1-9 below)

1. Recovery of Renal Function----- Yes  No

If yes,

a. Increased urine volume?----- Yes  No

If Yes, enter urine volume----- [ ][ ][ ][ ] mL/day

b. Spontaneous fall in serum creatinine?----- Yes  No

If Yes,

1. Current serum creatinine value----- [ ][ ] . [ ] mg/dL

a. Date obtained----- [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

2. Prior serum creatinine value----- [ ][ ] . [ ] mg/dL

a. Date obtained----- [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

c. Is measured creatinine clearance (by protocol specified urine collection) greater than 12 mL/min?----- Yes  No

2. Withdrawal of life-support-----

3. Patient Death (Complete Form 13)-----

4. Patient withdrawn from study (Complete Form 13)-----

5. Discharged/transferred from hospital on or before study day 28-----

6. Site terminated from study participation (Complete Form 13)-----

7. DSMB terminated study (Complete Form 13)-----

8. Reached study day 28-----

9. Other-----

Specify

[ ]

B. Was initial consent obtained by surrogate consent?----- Yes  No

If Yes, complete Form 2R (Re-Consent Form) if not previously completed.

Staff Initials

Date of Form Completion

[ ][ ] / [ ][ ] / [ ][ ]

[ ][ ][ ]

**L. Instructions for Form 11 – Day 28 Post-Randomization Status**

**Enter Hospital Number, Patient ID, Patient Initials, and the Date for Study Day 28.**

**When to complete this form: This form must be completed for every subject enrolled in the study. It should be completed on or as near as possible to study day 28 or day of exit from the study (i.e., a Form 13 has been completed for the subject), whichever comes first, to reflect the patient's status on study day 28 (or at time of study exit), even if the patient has discontinued study therapy before day 28 or before day of study exit. NOTE: Even if the patient has died or otherwise exited the study before study 28, this form must be completed.**

**A. Indicate the patient's vital status on study day 28 or on day of study exit, whichever comes first (where study day 28 is the 28<sup>th</sup> day in the study and day 1 is the day of randomization into the study). Check one box. If the patient has died or otherwise exited the study, be sure to also fill out Form 13 (Study Exit Form).**

**B. Assessment of Renal Function as of study day 28 or as of day of study exit.**

1. Mark 'yes' if the patient is still on/or at time of death was on dialysis/RRT; mark 'no' otherwise.

If the patient is **not still (or was not at time of death)** on dialysis,

- a. Enter the value of the most recent serum creatinine as mg/dL, or the lowest value if the patient developed subsequent acute renal failure post-study therapy.
- b. Enter the date on which the most recent serum creatinine recorded above was obtained as mm/dd/yy.
- c. Enter the date of the most recent treatment as mm/dd/yy.
- d. Enter the highest value obtained for the creatinine clearance prior to or on Day 28. If RRT was discontinued with a measured creatinine clearance >12 mL/min but <20mL/min, the creatinine clearance must be re-checked on or before Day 28 to demonstrate a value >20mL/min.

**C. The following information pertains to the hospitalization during which the patient was enrolled in the study.**

1. Enter the date of that hospitalization as mm/dd/yy.
2. Mark 'yes' if the patient was discharged from the hospital for that hospitalization on or before study day 28 or day of study exit; mark 'no' if the patient was not discharged from the hospital. (If the patient died during the hospitalization, s/he is considered to have been discharged on his/her date of death). If patient was discharged from or died during the hospitalization in which s/he was enrolled in the study, fill in the following information.
  - a. Date of discharge from the hospital as mm/dd/yy. (If patient died, the discharge date is date of death).
  - b. Discharge diagnosis information.
    1. Enter the primary discharge diagnosis.
    2. Enter the secondary discharge diagnosis.
  - c. Patient discharged to – choose **the one item** which best describes where the patient was discharged to. If 'other' is chosen, please specify what is meant in the box provided. If the hospital discharge was due to death, choose 'other' and specify 'DEATH' in the boxes provided.



**Instructions for Form 11 – Day 28 Post-Randomization Status**

**Enter Hospital Number, Patient ID, Patient Initials.**

**D. The following information pertains to the ICU stay during which the patient was enrolled in the study.**

1. Enter the date of the admission to the ICU as mm/dd/yy.
2. Mark 'yes' if the patient has been discharged from that ICU stay on or before study day 28 or study exit day; mark 'no' otherwise. If 'yes' is marked, enter the date of discharge from the ICU for that stay as mm/dd/yy. If the patient died during the ICU stay, mark 'yes' and enter the date of death as the date of discharge from the ICU.

**E. Mark 'yes' if the initial consent to participate in the study was obtained from a surrogate; mark 'no' otherwise. If 'yes' is marked, please be sure to complete Form 2R (Re-consent Form Cover Sheet) if not previously completed. If the patient has regained decision-making capacity, please be sure to re-consent the patient with the informed consent form (VA10-1086 for VA sites), if this has not already been done, and mail form 2R and a copy of the signed informed re-consent to WH CSPCC.**

Enter the date on which this form was completed as mm/dd/yy and enter the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 11 - DAY 28 POST - RANDOMIZATION STATUS

Hospital No.

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Patient ID

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Patient Initials

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NOTE: THIS FORM MUST BE COMPLETED FOR ALL SUBJECTS ENROLLED IN THE STUDY.

D. For the ICU Stay During Which Patient Entered the Study

1. Date of admission to ICU ----- 

--	--

 / 

--	--

 / 

--	--

 (mm/dd/yy)

2. Patient has been discharged from ICU? ----- Yes  No

If yes, date of discharge from ICU ----- 

--	--

 / 

--	--

 / 

--	--

 (mm/dd/yy)

E. Was initial consent obtained by surrogate consent? ----- Yes  No

If Yes, complete Form 2R (Re-Consent Form) if not previously completed.

Date of form completion

--	--

 / 

--	--

 / 

--	--

 (mm/dd/yy)

Staff Initials

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**M. Instructions for Form 12 – Day 60 Post-Randomization Status**

**Enter Hospital Number, Patient ID, Patient Initials, and Day-60 Post- Randomization Date.**

**When to complete this form: This form must be completed after study day 28 for every subject enrolled in the study and it should be completed on or as near as possible to study day 60 or day of exit from the study (i.e., a Form 13 has been completed), whichever comes first, to reflect the patient’s status on study day 60. NOTE: Even if the patient has died or otherwise exited the study before study day 60, this form must be completed. Obtain the information from the patient (if still hospitalized), from the medical record, or by telephone.**

**A. Indicate the patient’s vital status on study day 60 or day of exit from study, whichever comes first (remember that study day 1 is the day the patient was randomized into the study). Check one box.**

1. If the patient has died:
  - a. If death has occurred after study day 28, complete the remainder of this form and fill out Form 13 (Study Exit Form).
  - b. If death occurred on or before study day 28, make sure Form 11 and Form 13 are completed and skip to the end of this form.
2. If the patient is alive, complete the remainder of this form.

**B. Assessment of Renal Function as of study day 60 or day of exit from study.**

1. Mark ‘yes’ if the patient is still on or at the time of death was on dialysis/RRT; mark ‘no’ otherwise.  
If ‘no’,
  - a. Enter the value of the most recent serum creatinine as mg/dL or the lowest serum creatinine if the patient developed subsequent acute renal failure post-study.
  - b. Enter the date on which the serum creatinine recorded above was obtained.
  - c. Enter the date of the most recent treatment.

**C. The following information pertains to the hospitalization during which the patient was enrolled in the study.**

1. Enter the date of that hospitalization as mm/dd/yy.
2. Mark ‘yes’ if the patient was discharged from the hospital for that hospitalization on or before study day 60 or day of exit from study but after study day 28; mark ‘no’ if the patient was not discharged from the hospital. (If the patient died during the hospitalization, s/he is considered to have been discharged on his/her date of death). If the patient was discharged from or died during the hospitalization in which s/he was enrolled in the study, fill in the following information.
  - a. Date of discharge from the hospital as mm/dd/yy. (If patient died, the discharge date is date of death).
  - b. Discharge diagnosis information.
    1. Enter the primary discharge diagnosis.
    2. Enter the secondary discharge diagnosis.



**Instructions for Form 12 – Day 60 Post-Randomization Status**

**Enter Hospital Number, Patient ID, and Patient Initials**

- c. Patient discharged to – choose **the one item** which best describes where the patient was discharged to. If ‘other’ is chosen, please specify what is meant in the boxes provided. If the hospital discharge was due to death, choose ‘other’ and specify ‘DEATH’ in the boxes provided.

**D. The following information pertains to the ICU stay during which the patient was enrolled in the study.**

1. Enter the date of the admission to the ICU as mm/dd/yy.
2. Mark ‘yes’ if the patient has been discharged from that ICU stay on or before study day 60 or day of exit from study and after study day 28; mark ‘no’ otherwise. If ‘yes’ is marked, enter the date of discharge from the ICU for that stay as mm/dd/yy. If the patient died during the ICU stay on or before study day 60 or day of exit from study but after study day 28, mark ‘yes’ and enter the date of death as the date of discharge from the ICU.

**E. Mark ‘yes’ if the initial consent to participate in the study was obtained from a surrogate; mark ‘no’ otherwise. If ‘yes’ is marked, please be sure to complete Form 2R (Re-consent Form Cover Sheet) if not previously completed. If the patient has regained decision-making capacity, be sure to re-consent the patient with the informed re-consent form (VA10-1086 for VA sites), if this has not already been done, and mail form 2R and a copy of the signed informed re-consent to WH CSPCC.**

Enter the date on which this form was completed as mm/dd/yy and enter the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 12 - DAY 60 POST - RANDOMIZATION STATUS

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

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NOTE: THIS FORM MUST BE COMPLETED BY ALL SUBJECTS ENROLLED IN THE STUDY

c. Patient discharged to (choose one):

- Home
- Skilled Nursing Facility
- Assisted Living Facility

Other, specify:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

D. For the ICU Stay During Which Patient Entered Study

1. Date of admission to ICU ..... 

--	--

 / 

--	--

 / 

--	--

 (mm/dd/yy)

2. Patient has been discharged from ICU ..... Yes  No

If yes, date of discharge from ICU ..... 

--	--

 / 

--	--

 / 

--	--

 (mm/dd/yy)

E. Was initial consent obtained by surrogate consent? ..... Yes  No

If Yes, complete Form 2R (Re-Consent Form) if not previously completed.

Date of Form Completed

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 / 

--	--

 / 

--	--

 (mm/dd/yy)

Staff Initials

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**N. Instructions for Form 13 – Study Exit Form**

**Enter Hospital Number, Patient ID, Patient Initials, and the Date Form Completed.**

**When to complete this form: Complete this form on study day 60 or the day the patient exits from the study if that exit date is before study day 60. This form must be completed for every subject enrolled in the study. Obtain the information from the patient (if still hospitalized), from the medical record, or by telephone.**

**I. Mark ‘yes’ if initial consent was obtained by a surrogate; mark ‘no’ if the patient gave the initial consent to participate in the study. If ‘yes’ is marked, please complete Form 2R (Re-consent Form Cover Sheet) if not previously completed. If the patient has regained decision-making capacity, please re-consent the patient (see Section VI of the Ops Manual), if this has not already been done, and mail form 2R and a copy of the signed informed re-consent to WH CSPCC.**

**II. REASON FOR EXIT FROM THE STUDY (Mark only one of the items below)**

**Death:** Mark if death was the reason for exit from the study, and enter the date of death as mm/dd/yy.

1. Mark ‘yes’ if the death certificate is attached; mark ‘no’ otherwise.
2. Mark ‘yes’ if the patient was still on dialysis/RRT at time of death; mark ‘no’ otherwise.

**Completion of 60-day follow-up:** Mark if study exit was due to end of 60-day follow-up and enter date of 60-day follow-up as mm/dd/yy.

**Lost to follow-up:** Mark if study exit was due to the patient being lost to follow-up and enter the date of last contact with the patient as mm/dd/yy.

**Termination of the site from study participation:** Mark if the study was terminated prematurely at your site and enter the date that the study was terminated at your site as mm/dd/yy.

**Withdrew (withdrawal of the patient from the study by the patient, by patient’s physician, or by the patient’s surrogate):** Mark if study exit was due to withdrawal of the patient from the study and enter the date of withdrawal as mm/dd/yy.

1. Indicate the reason for withdrawal (Choose only one)
2. If ‘Protocol Violation’ or ‘Other’, specify reason.

VA WEST HAVEN CP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 13 - STUDY EXIT

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

Date Form Completed (mm/dd/yy)

[ ][ ] / [ ][ ] / [ ][ ]

NOTE: THIS FORM MUST BE COMPLETED FOR ALL SUBJECTS ENROLLED IN THE STUDY.

I. Was initial consent obtained by surrogate consent? ..... Yes  No   
If Yes, complete Form 2R (Re-Consent Form) if not previously completed.

II. Reason for Subject's exit from the study (Choose one):

Death

If patient died, date of Death ..... [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

1. Death certificate attached ..... Yes  No

2. Was patient still on dialysis/RRT at time of death? ..... Yes  No

Completion of 60-day follow-up

Date of 60-day follow-up ..... [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

Lost to follow-up

If lost, date of last contact ..... [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

Termination of site from study participation

If terminated, date of site termination ..... [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

Withdrew

If withdrawn, date of withdrawal ..... [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

1. Reason for withdrawal (choose one)

Patient withdrew consent

Surrogate withdrew consent

MD withdrawal of patient from study

Discontinued due to Serious Adverse Event (If SAE is treatment related, complete Form 16)

Patient transferred to another acute care hospital

Protocol violation (Specify)

[ ]  
[ ]

Other (Specify)

[ ]  
[ ]

Staff Initials [ ][ ][ ]

**O. Instructions for Form 14 – Release of Information**

**Enter the Hospital Number, Patient ID, Patient Initials and Date Form Completed.**

**When to have the patient sign this form:**

1. If the patient is able to give consent and sign the informed consent at enrollment time, this form should be signed by the patient at the same time the informed consent is signed.
2. If surrogate consent was given for the patient to enroll in the study, the patient will be asked to re-consent to CSP 530 if he/she recovers decision-making capacity. Present Form 14 to the patient to be signed at that time of re-consent.
3. After the patient's signature has been obtained and the date form signed is filled in (as mm/dd/yy), enter the initials of the staff member who obtained the signature at the bottom of the form.

**When to use**

A **photocopy** of the signed and dated Form 14 must be completed for each inpatient stay outside the original study site. Inpatient stays include stays at hospitals, nursing homes, and hospices. Mail the completed Form 14 and a cover letter (see below) to the facility at which the stay occurred. **You must also mail a photocopy of each completed Form 14 to the West Haven CSPCC.**

**Exception:** Form 14 is not required for stays within the VA system, even if they occur outside the VA facility where the patient was originally hospitalized.

Example: A VA patient is originally hospitalized at the San Francisco VA. Later he stays at the Palo Alto VA hospital. Form 14 is not required.

Inpatient stays are recorded on Forms 17V and 18V for patients enrolled at VA study sites, and on Forms 17N and 18N for patients enrolled at all other study sites. If you see any inpatient stays recorded on those forms, a request for information must be made using a photocopy of this form.

**Caution:** Be sure to keep the original Form 14. **Do not mail the original to anyone!**

**Data to enter**

1. Enter the patient's name and date of birth as mm/dd/yyyy.
2. Enter the admission date to the non-study facility as mm/dd/yy for:
  - a. The Discharge Summary Requested.
  - b. The Billing Record Requested.
3. Enter the contact name and address for the non-study facility from which information is being requested.

**What to send**

1. To the non-study facility (hospital, nursing home, or hospice):
  - a. a completed photocopy of Form 14.
  - b. a cover letter with the following information:
    - who is requesting the information;
    - what information is requested and for what purpose it will be used;
    - a signed and dated Release of Information is enclosed; and
    - where that information should be sent (to Mark Smith at HERC).

**A sample cover letter appears on the next page.**

2. To the West Haven CSPCC:
  - a. a photocopy of the completed Form 14
  - b. a photocopy of the cover letter
3. To Mark Smith at HERC (see address on Form 14):
  - a. a photocopy of the completed Form 14
  - b. (optional) a photocopy of the cover letter

*continued on next page*

**Sample Cover Letter to Accompany Form 14 (Release of Information)**

*Today's date*

Dear Sir or Madam:

Mr. John Q. Patient is a participant in a randomized clinical trial sponsored by the National Institutes of Health (NIH) and the U.S. Dept. of Veterans Affairs (VA). The study, "Intensive vs. Conventional Renal Support in Acute Renal Failure," is a randomized clinical trial being carried out by the VA Cooperative Studies Program (CSP Trial #530). It has the potential to save thousands of lives each year through improved treatment of acute renal failure.

The participant has informed us that he/she was recently admitted to your institution. Enclosed is a signed Release of Information form that authorizes you to send us protected health information about the person's stay. Please send copies of the discharge summary and billing record to Dr. Mark Smith at the address given below.

Please contact Dr. Smith if you have any questions or comments about this study or the enclosed request. You may also contact either of the CSP #530 study investigators listed below.

I greatly appreciate your time and effort in fulfilling this request.

Sincerely,

Mark W. Smith, Ph.D.  
Investigator, CSP #530  
HERC  
VA Health Economics Resource Center  
765 Willow Road (152MPD)  
Menlo Park, CA 94025  
Phone (650) 617-2630

Paul Palevsky, MD	<i>Name of Local Site PI, M.D.</i>
Principal Investigator, CSP # 530	Investigator, CSP #530
Room 7E123 (111F-U)	<i>address</i>
VA Pittsburgh Healthcare System	<i>address</i>
University Drive Division	<i>address</i>
Pittsburgh, PA 15240-0001	<i>telephone</i>
(412) 688-6000 x5932	

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 14 - RELEASE OF INFORMATION

Hospital No.

Patient ID

Patient Initials

Date Form Completed (mm/dd/yy)

This form authorizes the disclosure of protected health information, as described below.

Patient's Name and Date of Birth

Patient's First Name

M.I.

Last Name

Date of Birth

 (mm/dd/yyyy)

What Information May be Disclosed?

Discharge Summary -----

Admission Date

Billing Record -----

Admission Date

Who May Disclose the Information?

Facility

Number & Street Address

City

State

Zip Code

Who May Receive and Use the Information:

Staff members, investigators, and researchers affiliated with the ARF Treatment Network Trial (VA CSP #530) or with the Veterans Health Administration.

Mail records and a copy of this form to:

ARF Treatment Network (ATN) Trial (CSP #530)  
c/o Mark Smith, PhD  
HERC  
VA Palo Alto Healthcare System  
795 Willow Rd (MPD 152)  
Menlo Park, CA 94025

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 14 - RELEASE OF INFORMATION

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

--	--	--

Date Form Completed (mm/dd/yy)

		/			/		
--	--	---	--	--	---	--	--

**Authorization Statement:**

I hereby authorize disclosure of the information described above. I understand the following:

1. The information will be used for research and to improve the quality of health care;
2. There is no expiration date for the authorization;
3. I may refuse to sign this authorization, and refusal will not affect my ability to participate in the ATN Trial;
4. I may revoke this authorization at any time by making a written request;
5. If I revoke this authorization, it will not apply to actions taken earlier.

\_\_\_\_\_  
Print Name of Patient

\_\_\_\_\_  
Signature of Patient

		/			/		
--	--	---	--	--	---	--	--

 (mm/dd/yy)  
Date Signed

Staff Initials

--	--	--

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**P. Instructions for Form 15 – Dialysis Catheter Insertion Form**

**Enter Hospital Number, Patient ID, Patient Initials, Date Catheter Inserted, and Catheter No. inserted this date (enter 1 for first catheter inserted on this date, 2 for second catheter inserted on this date, etc) at the top of every page of this form.**

**When to complete this form: This form should be completed for each dialysis catheter insertion/change while the patient is on study therapy. Please use one form for each dialysis catheter and keep track of the total number of dialysis catheter insertions during the time the patient is receiving the study therapy. Fill out items 1 through 9 when the catheter is inserted and complete the remainder of the form when the catheter is removed.**

1. Enter the number indicating to which study catheter (over the entire period the patient is receiving study therapy) this data applies. Please enter the leading zero for catheters 01 through 09.
2. Time dialysis catheter inserted-
  - a. Enter the time the catheter was inserted as military time; e.g., 8:00am is 0800, noon is 1200, and 8:00pm is 2000.
  - b. Check this box if the time of catheter insertion is unknown.
3. Mark 'yes' if the catheter was placed through an existing vascular access site; mark 'no' otherwise.
4. Mark 'yes' if the catheter was placed through a new vascular access site; mark 'no' otherwise.  
**Note: If the answer to question 3 is 'yes' then the answer to question 4 must be 'no' and vice-versa.**
5. Mark 'yes' if this was a tunneled catheter; mark 'no' otherwise.
6. If there were two (2) lumens, check the box marked 'two'; if there was some other number of lumens, check the box marked 'other' and specify in the text box provided.
7. Enter the 3-digit code for the Catheter Type (see the coding section of the Ops Manual).
8. Location of the catheter (choose one only). If 'other' is chosen, please specify the location in the text box provided.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 15 - DIALYSIS CATHETER INSERTION FORM

Hospital No.	Patient ID	Patient Initials	Date Catheter Inserted (mm/dd/yy)	Catheter No. This Date
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

NOTE: COMPLETE THIS FORM FOR EACH DIALYSIS CATHETER INSERTION/CHANGE. USE ONE FORM FOR EACH DIALYSIS CATHETER.

1. Catheter number over the entire study period.   
(e.g., first study catheter = 01, second study catheter = 02, ..., tenth study catheter = 10, ..., fifteenth study catheter=15)

2. Time dialysis catheter inserted  
a. Military time  hours      b.  Time unknown

3. Dialysis catheter placed through existing vascular access site .....  yes     no

4. Dialysis catheter placed through new vascular access site .....  yes     no

5. Tunneled Catheter .....  yes     no

6. Number of lumens (choose one) :     Two     Other, specify

7. Catheter Type  (see Ops Manual)

8. Location of dialysis catheter (choose one):  
 subclavian  
 internal jugular  
 femoral  
 other, specify

**Instructions for Form 15 – Catheter Insertion Form**

**Enter Hospital Number, Patient ID, Patient Initials, Date Catheter Inserted, and Catheter No. inserted this date (enter 1 for first catheter inserted on this date, 2 for second catheter inserted on this date, etc) at the top of every page of this form.**

9. Insertion complications occurring within 24 hours of catheter placement.

Mark 'yes' for all complications that occurred within 24 hours of catheter placement, and for each complication that was a serious one, mark the 'SAE' box to the right of the 'yes' box and complete a Serious Adverse Event Form (Form 16) for each complication for which the "SAE" box has been marked; mark 'no' for all complications that did not occur.

If the 'yes' box is marked for 'other', please specify what the complication was in the text box provided.

10. Insertion complications occurring more than 24 hours after catheter placement.

Mark 'yes' for all complications that occurred more than 24 hours after catheter placement, and for each complication that was a serious one, mark the 'SAE' box to the right of the 'yes' box and complete a Serious Adverse Event Form (Form 16) for each complication for which the "SAE" box has been marked; mark 'no' for all complications that did not occur.

If the 'yes' box is marked for 'other', please specify what the complication was in the text box provided.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 15 - DIALYSIS CATHETER INSERTION FORM

Hospital No.	Patient ID	Patient Initials	Date Catheter Inserted (mm/dd/yy)	Catheter No. This Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>

9. Insertion complications within 24 hours of catheter placement.
- |                                            | No                       | Yes                      | If yes, check if it was an SAE* |
|--------------------------------------------|--------------------------|--------------------------|---------------------------------|
| a. catheter-related infection-----         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| b. cardiac arrythmia -----                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| c. pneumothorax -----                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| d. hemothorax-----                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| e. inadvertent arterial puncture-----      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| f. excess bleeding at insertion site ----- | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| g. local venous thrombosis -----           | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| h. venous thromboembolism -----            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| i. air embolism -----                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| j. other -----                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |

If other, specify

10. Late complications (>24 hours from placement to 3 days after removal).
- |                                           | No                       | Yes                      | If yes, check if it was an SAE* |
|-------------------------------------------|--------------------------|--------------------------|---------------------------------|
| a. catheter-related infection -----       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| b. cardiac arrythmia -----                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| c. pneumothorax -----                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| d. hemothorax -----                       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| e. inadvertent arterial puncture-----     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| f. catheter-associated bacteremia -----   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| g. excess bleeding at insertion site----- | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| h. local venous thrombosis -----          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| i. venous throembolism -----              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| j. air embolism -----                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |
| k. other -----                            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>        |

If other, specify

\*NOTE: IF ANY OF THE COMPLICATIONS WERE SERIOUS ADVERSE EVENTS, CHECK THE SAE BOX FOR THE EVENT AND COMPLETE FORM 16 FOR EACH SAE.

**Page 3 of 4**

**Instructions for Form 15 – Catheter Insertion Form**

**Enter Hospital Number, Patient ID, Patient Initials, Date Catheter Inserted, and Catheter No. inserted this date (enter 1 for first catheter inserted on this date, 2 for second catheter inserted on this date, etc) at the top of every page of this form.**

11. Date and time catheter removed-

- a. Enter the date the catheter was removed as mm/dd/yy.
- b. Enter the time the catheter was removed as military time; e.g., 8:00am is 0800, noon is 1200, and 8:00pm is 2000.
- c. Check this box if the time of catheter removal is unknown.

12. Mark the box that best indicates the reason the catheter was removed. Mark one box only. If 'other' is marked, please specify the reason in the text box provided.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 15 - DIALYSIS CATHETER INSERTION FORM

Hospital No.	Patient ID	Patient Initials	Date Catheter Inserted (mm/dd/yy)	Catheter No. This Date
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

11. Date and time catheter removed

a. Date  /  /  (mm/dd/yy)

b. Military time  hours

c.  Time unknown

12. Reason catheter removed (choose one):

- catheter complication
- catheter malfunction
- routine line change
- catheter-associated bacteremia
- exit site infection
- recovery of renal function (catheter no longer required)
- other, specify

**Instructions for Form 15 – Catheter Insertion Form**

**Enter Hospital Number, Patient ID, Patient Initials, Date Catheter Inserted, and Catheter No. inserted this date (enter 1 for first catheter inserted on this date, 2 for second catheter inserted on this date, etc) at the top of every page of this form.**

13. Mark 'yes' if cultures were obtained; mark 'no' otherwise.

If 'yes',

a. Mark 'yes' if the exit site was cultured; mark 'no' otherwise;

If the exit site was cultured, code the culture results for up to four (4)

organisms (see the coding section of the Ops Manual); i.e., if a culture was positive for one organism, enter the code for that organism in the boxes on line 1 (organism 1); if a culture was positive for two organisms, enter the code for the first organism in the boxes on line 1 and the code for the second organism in the boxes on line 2, etc. If all results were negative, then code '00' in the 2 boxes for organism 1 on line 1.

b. Mark 'yes' if the catheter tip was cultured; mark 'no' otherwise;

If the catheter tip was cultured, code the culture results and the colony count (colony forming units, cfu) value for up to four (4) organisms (see the coding section of the Ops Manual); i.e., if a culture was positive for one organism, enter the code for that organism and the cfu value in the boxes on line 1 (organism 1); if a culture was positive for two organisms, enter the code for the first organism and the cfu value in the boxes on line 1 and the code for the second organism and the cfu value in the boxes on line 2, etc. If all results were negative, then code '00' in the 2 boxes for organism 1 on line 1.

c. Mark 'yes' if blood cultures were obtained for catheter associated bacteremia; mark 'no' otherwise. If blood cultures were obtained for catheter associated bacteremia, code the culture results for up to four (4) organisms (see the coding section of the Ops Manual); i.e., if a culture was positive for one organism, enter the code for that organism in the boxes on line 1 (organism 1); if a culture was positive for two organisms, enter the code for the first organism in the boxes on line 1 and the code for the second organism in the boxes on line 2, etc. If all results were negative, then code '00' in the 2 boxes for organism 1 on line 1.

Enter the date form completed as mm/dd/yy and the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 15 - DIALYSIS CATHETER INSERTION FORM

Hospital No.	Patient ID	Patient Initials	Date Catheter Inserted (mm/dd/yy)	Catheter No. This Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>

13. Were cultures obtained?-----  yes  no

If yes,

a. Exit site cultured?-----  yes  no

If yes, culture results (See Ops Manual):

1. organism 1	<input type="text"/>
2. organism 2	<input type="text"/>
3. organism 3	<input type="text"/>
4. organism 4	<input type="text"/>

b. Catheter tip cultured?-----  yes  no

If yes, culture results (See Ops Manual):

1. organism 1	<input type="text"/>	cfu	<input type="text"/>
2. organism 2	<input type="text"/>	cfu	<input type="text"/>
3. organism 3	<input type="text"/>	cfu	<input type="text"/>
4. organism 4	<input type="text"/>	cfu	<input type="text"/>

c. Blood cultures obtained for catheter associated bacteremia?-----  yes  no

If yes, culture results (see Ops Manual):

1. organism 1	<input type="text"/>
2. organism 2	<input type="text"/>
3. organism 3	<input type="text"/>
4. organism 4	<input type="text"/>

Date of Form Completion

/  /  (mm/dd/yy)

Staff Initials

**Page Intentionally Left Blank**

## Q. General Instructions for Form 16 – Serious Adverse Event Form

Enter Hospital Number, Patient ID, Patient Initials, the Date of Onset of the SAE and the number that indicates which SAE this is for this date of onset (e.g., if only one SAE is being reported for this date of onset, code '01' in these 2 boxes; if 2 SAE's have the same date of onset, use a separate Form 16 for each, and code '01' in these 2 boxes for one of them and code '02' in these 2 boxes for the other. If five SAE's have the same date of onset, you will use five SAE forms, and code '01', '02', '03', '04', and '05' in these 2 boxes for the first through fifth SAE form, respectively.)

### DEFINITIONS:

1. **Serious Adverse Event (SAE):** Any untoward medical occurrence that results in death, is life-threatening (places the patient at risk of death), prolongs existing hospitalization, results in persistent or significant disability/incapacity, or otherwise is considered serious by the principle investigator.
2. **Study intervention:** The renal replacement therapy. This is the intensive or conventional renal support provided during the study.
3. **Definitely Related SAE:** A serious adverse event that has a reasonable causal relationship with the study intervention. A definite causal relationship exists. (i.e., timing of event means a cause and effect did occur, all catheter related serious adverse events)
4. **Possibly/Probably Related SAE:** A serious adverse event that has a reasonable causal relationship with the study intervention. A definite causal relationship does not need to exist or be proven. (i.e., other events where other causes may have resulted in the event, but a relationship cannot be ruled out).
5. **Expected SAE:** An expected event is one that is known and has previously been observed in patients on dialysis. These will include events previously reported in the literature as a result of dialysis therapy. Examples of expected events include items in the informed consent document such as hypotension, electrolyte abnormalities, infection, and death. Death from any underlying cause is not unexpected since the literature reports a death rate of approximately 50% in patients with acute tubular necrosis placed on dialysis.
6. **Unexpected SAE:** An unexpected event will generally involve an adverse experience previously unobserved or undocumented in patients as a result of them getting dialysis or having a dialysis catheter placement. An unexpected event is one that is not consistent with the information known in the medical literature about the study intervention. Unexpected events are very rare and represent a new safety risk involving dialysis that we do not currently know about.

## Guidelines for SAE Reporting of Hypotension During Study Therapy

Hypotension is a common and expected complication of renal replacement therapy, particularly in patients with underlying hemodynamic instability. Although the majority of episodes of hypotension associated with renal replacement therapy are likely to be transient and not life threatening, a substantial number may be severe enough to warrant reporting as Serious Adverse Events. Although the determination of whether a particular episode should be reported is **at the discretion of the site investigator**, the following criteria provide **general guidance** for when hypotension during study therapy should be reported as a Serious Adverse Event:

1. Hypotension requiring discontinuation of study treatment (e.g., premature termination of an intermittent hemodialysis treatment, with or without conversion to CVVHDF or SLED would probably constitute an SAE);
2. Hypotension requiring initiation or significant escalation of vasopressor therapy (e.g., a sustained increase in dopamine dose from 4 to 20 mcg/kg/min or the addition of norepinephrine to a maximal rate of dopamine infusion would probably constitute SAEs while an increase in dopamine infusion from 4 to 6 mcg/kg/min would probably not constitute an SAE.); or
3. Hypotension that results in an associated untoward event (e.g., an episode of hypotension that results in signs or symptoms of myocardial, cerebrovascular or mesenteric ischemia).

**Instructions for Form 16 – Serious Adverse Event Form**

**NOTES:**

1. Complete this form for all deaths that occurred within 30 days of randomization (regardless of the cause of death).
2. For other SAEs (not death) all three of the following must be true before completing Form 16:
  - a. The SAE occurred within 30 days of randomization.
  - b. The adverse event was serious. (Defined above.)
  - c. The event was thought to be definitely or possibly/probably related to the study intervention. (Defined above).
3. Complete this form for all complications of catheter insertion that were serious complications.
4. Notify the West Haven CSPCC of all Serious Adverse Events for which a Form 16 is being completed within 72 hours of becoming aware of the SAE. Inform West Haven CSPCC by phoning and by FAXING them a copy of this form.
5. You must also notify your IRB of SAEs in accordance with local IRB policy.

**INSTRUCTIONS:**

1. Type of SAE report – check one box only. If this is the initial report for this ‘SAE’, mark the ‘initial’ box; if this is a follow-up report for this ‘SAE’, mark the ‘follow-up’ box; if this is the final report for this event, mark the ‘final’ box. If only one report will be submitted for this event (i.e., this is both the initial and final report for the event –this occurs when the SAE is resolved at the time of the report), mark the ‘initial’ box. All other initial reports where the SAE has not resolved must have a follow-up or final report completed when the SAE is resolved, death occurs, at hospital discharge or within 30 days post-randomization, whichever comes first.
2. SAE criteria. Check items ‘a’ through ‘e’ below that apply to this SAE. More than one SAE criteria may be checked. If ‘other’ is checked, please specify details in the text boxes provided.
3. Indicate whether the serious adverse event was expected or unexpected. (Defined above).  
This question can be confusing to answer when a patient dies or has a serious adverse event that the health care team does not anticipate to happen considering the patient’s underlying disease(s). An adverse event that is not anticipated to occur by the health care team and is associated with the patient’s disease state(s) (not the dialysis or dialysis catheter) is NOT UNEXPECTED for question #3.
4. Briefly describe the SAE by giving the diagnosis, a keyword, or a laboratory parameter that best tells about this SAE.
5. Describe the event using symptoms, signs, and time course.
6. Enter the code for this Serious Adverse Events (see coding section of the Ops Manual). If no code is available, the event code 999 can be used. Do not attempt to use an event code that does not accurately describe the adverse event. In these cases, it is best to use 999.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 16 - SERIOUS ADVERSE EVENT

Hospital No.	Patient ID	Patient Initials	Date of Serious Adverse Event Onset	SAE No. this date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> (mm/dd/yy)	<input type="text"/>

NOTES:

1. Only complete this form for SAEs occurring within 30 days of randomization.
2. Complete this form if a death occurred or if the event was both serious and thought to be related to the study therapy.
3. PLEASE NOTIFY THE WEST HAVEN CSPCC BY TELEPHONE AND BY FAXING THEM A COPY OF THIS FORM WITHIN 72 HOURS OF BECOMING AWARE OF THIS SAE.
4. You must also notify your IRB of SAEs in accordance with local IRB policy.

1. Type of SAE report (check one) .....  Initial     Follow-up     Final
2. SAE Criteria (check all that apply)
  - a.  Death [Fill out Form 13 (Study Exit) and complete remainder of this form]
  - b.  Life-threatening
  - c.  Disability/Incapacity
  - d.  Prolonged existing hospitalization
  - e.  Other event felt to be serious by the investigator (Specify)


3. Was the Serious Adverse Event (check one)     Expected\*     Unexpected\*  
\*See Ops Manual for definitions.

4. Serious Adverse Event (use diagnosis, keyword, or lab parameter)

--

5. Description (describe event, using symptoms, signs, and time course)


6. Serious Adverse Event Code\* .....

\*USE SERIOUS EVENT CODE LIST PROVIDED IN OPERATIONS MANUAL.  
If the description of the event does not match any of the SAE codes, fill in 999.

**Instructions for Form 16 – Serious Adverse Event Form**

**Enter Hospital Number, Patient ID, Patient Initials, the Date of Onset of the SAE and the number that indicates which SAE this is for this date of onset (e.g., if only one SAE is being reported for this date of onset, code ‘01’ in these 2 boxes; if 2 SAE’s have the same date of onset, use a separate Form 16 for each, and code ‘01’ in these 2 boxes for one of them and code ‘02’ in these 2 boxes for the other. If five SAE’s have the same date of onset, you will use five SAE forms, and code ‘01’, ‘02’, ‘03’, ‘04’, and ‘05’ in these 2 boxes for the first through fifth SAE form, respectively.)**

7. Check the action taken with respect to renal replacement therapy as a result of the serious adverse event. Check one item only. If ‘other’ is checked, please specify action taken in the text box provided. If the study therapy was permanently discontinued, please complete Form 10, Discontinuation of Study Therapy Form.
8. Relationship of the SAE to the study intervention.
  - a. If the serious adverse event resulted in patient death, check one of the three boxes shown in 8.a.
  - b. If the SAE was a non-death, check one of the two boxes shown in 8.b. Note: If the SAE is NOT related to the study intervention, do not fill out Form 16.
9. Final outcome – check one item only to indicate the worst outcome.
  - a. Check this box if the SAE is still present at the time of this report. If this is the initial report for this SAE and the SAE is still present at the time of this report, please be sure to send a follow-up or final Form 16 for this SAE with information current through when the SAE is resolved, death occurred, hospital discharge occurred, or 30 days post-randomization, whichever comes first.
  - b. Check this box if a chronic condition or sequelae resulted from this SAE.
  - c. Check this box if the outcome of this SAE was death. Also complete Form 13, Study Exit Form.
  - d. Check this box if the worst outcome was that the SAE resolved and there were no sequelae. Give the date on which the SAE resolved.

Enter the signature of the person completing the form and the date of form completion as mm/dd/yy.

Enter the signature of the PI and the date the PI signed the form as mm/dd/yy..

Enter the initials of the staff person completing this form.

**NOTE: Timely completion of the form and the PI signature is required. If an unexpected delay in getting the PI signature occurs, the form should be faxed to the West Haven CSPCC within 72 hours of learning of the SAE without the PI signature. A second copy of this form with the signature of the PI should be mailed to the West Haven CSPCC as soon as the PI signature is available. Remember to report SAEs to your IRB according to local IRB policy.**

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 16 - SERIOUS ADVERSE EVENT

Hospital No.	Patient ID	Patient Initials	Date of Serious Adverse Event Onset	SAE No. this date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> (mm/dd/yy)	<input type="text"/>

7. Action taken with respect to Renal Replacement Therapy (check one)

- Patient was not on RRT at time of the event
- Temporarily interrupted
- Not interrupted
- Other, specify:
- Treatment discontinued
- Study therapy permanently discontinued\*

\*NOTE: IF STUDY THERAPY PERMANENTLY DISCONTINUED, COMPLETE FORM 10.

8. Relationship of the Serious Adverse Event to the Study Intervention\*

a. If event was death (check one):

- Definitely related
- Possibly/Probably related
- Not related

b. For all non-death events (check one):

- Definitely related
- Possibly/Probably related
- Other

\*See Ops Manual for definitions of relatedness

9. Final Outcome (Check one item only to indicate the worst outcome)

- a.  SAE still present at time of report\*
- b.  Chronic condition or sequelae resulted from SAE
- c.  Death [Complete Form 13 (Study Exit Form)]
- d.  SAE resolved-No sequelae

i. Date SAE resolved/no longer SAE -----  /  /   
(mm/dd/yy)

\*NOTE: If this is the initial report and the SAE is still present at the time of this report, be sure to send a follow-up or final Form 16 for the event with information current through when the SAE is resolved, death, hospital discharge, or 30 days post-randomization, whichever comes first.

\_\_\_\_\_  
Signature of person completing form

/  /   
Date of Form Completion (mm/dd/yy)

\_\_\_\_\_  
PI Signature

/  /   
Date PI Signed (mm/dd/yy)

Staff Initials

**Page 1 of 6**

**R. Instructions for Form 17N – 60 Day Follow-up for Non-VA Patients**

**\*\*\*This form is for use by Hospitals number 901 through 910 only.**

**When to complete**

The 60<sup>th</sup> day after enrollment is called “Day 60.” Complete Form 17N on Day 60 or as soon as possible afterward. Data should be provided by the patient, or by the patient contact listed on Form 5.

Complete this form only if the patient was discharged alive from the original hospital stay. If you learn that the patient died after hospital discharge but before Day 60, you may complete the form prior to Day 60.

If the patient is well enough to give consent but has not re-consented to the study, complete only questions 1 and 2. Then send the re-consent form to the patient. You must receive it back from the patient before completing questions 3-15. You must also complete Form 2R. Remember to mail the completed Form 17N, Form 2R, and a copy of the signed re-consent form to WH CSPCC.

**Enter at top**

- Hospital number (of the study hospital)
- Patient’s ID and initials
- Date the form was completed

**Enter in gray box**

- Discharge Date (from the hospitalization during which the patient entered the study)
- Day 60 date (or death date, if before Day 60)

1. Mark ‘yes’ if the patient has been hospitalized continuously since enrollment; mark ‘no’ otherwise.

- If ‘yes,’ you are done. Leave the remainder of the form blank.
- If ‘no,’ complete the remainder of this form.

2. Mark ‘yes’ if the patient has died; mark ‘no’ otherwise.

If the patient has died, enter the date of death in item (a) and complete the remainder of the form by asking the patient’s contact person for any needed information.

**Caution:** The patient must sign and return a re-consent form, if he/she is able, before the rest of this form may be completed.

3. Ask about inpatient hospitalizations outside the study hospital between the Discharge Date and Day 60 (or death date). Mark ‘yes’ if there were any such events; mark ‘no’ otherwise and skip to question 4. If yes, enter

- a. admission date
- b. facility name
- c. facility city and state
- d. number of days the patient stayed there
- e. number of days the patient was in the ICU (for hospitalizations only)
- f. Mark ‘yes’ if there have been additional hospital admissions; mark ‘no’ otherwise. If ‘yes,’ fill in the information concerning additional hospitalizations on the continuation sheets on pages 4 and 5 of this form.



**Page 2 of 6   Instructions for Form 17N – 60 Day Follow-up for Non-VA Patients**

**Enter at top**

- Hospital number
  - Patient's ID and initials
- 
4. Ask about nursing home stays between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such events; mark 'no' otherwise and skip to question 5. If yes, enter
    - a. admission date
    - b. facility name
    - c. facility city and state
    - d. number of days the patient stayed there
    - e. Mark 'yes' if there have been additional nursing home stays; mark 'no' otherwise. If 'yes,' fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.
  
  5. Ask about hospice stays between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such events; mark 'no' otherwise and skip to question 6. If yes, enter
    - a. admission date
    - b. facility name
    - c. facility city and state
    - d. number of days the patient stayed there
    - e. Mark 'yes' if there have been additional hospice stays; mark 'no' otherwise. If 'yes,' fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.



**Page 3 of 6 Instructions for Form 17N – 60 Day Follow-up for Non-VA Patients**

**Enter at top**

- Hospital number
  - Patient's ID and initials
6. Ask about medical appointments between the Discharge Date and Day 60 (or death date) that were for kidney problems and occurred outside the study hospital. Mark 'yes' if there were any; mark 'no' otherwise and skip to question 7.
- a. Enter the number of medical appointments the patient had for kidney problems outside of the study hospital.
  - b. Enter the average number of miles traveled each way for these appointments.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
7. Ask about regular kidney dialysis treatments outside the study hospital that occurred between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such treatments; mark 'no' otherwise and skip to question 8.
- a. Enter the number of times per week the patient received regular kidney dialysis treatments outside the study hospital.
  - b. Enter the average number of miles traveled each way for these treatments.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
8. Ask about visits to healthcare providers outside the study hospital for a reason other than kidney problems, between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such visits; mark 'no' otherwise and skip to question 9.
- a. Enter the number of times a health care provider outside the study hospital was seen for other than kidney problems.
  - b. Enter the average number of miles traveled each way for these visits.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
9. Mark 'yes' if someone helped the patient around the house with healthcare, such as changing bandages or giving medications, between the Discharge Date and Day 60 (or death date); mark 'no' otherwise. If 'yes,'
- a. Enter the number of hours per week someone helped with such healthcare.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL (ATN STUDY)  
FORM 17N - 60 DAY FOLLOW-UP FOR NON-VA PATIENTS

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

--	--	--

Now I'd like to ask about outpatient care, such as doctor appointments and visits to kidney dialysis clinics. Do not include any stays in a hospital, nursing home, or hospice.

6. Between \_\_\_\_\_ and \_\_\_\_\_, have [you/patient] had any  
(Discharge date) (Day-60)

medical appointments outside the study hospital concerning your kidney  
problems?-----

Yes No

If yes,

a. How many medical appointments?-----

--	--

b. How many miles each way did [you/patient] travel, on average?-----

--	--	--

 miles

c. Did someone go with [you/patient] most times?-----

Yes No

7. Between \_\_\_\_\_ and \_\_\_\_\_, have [you/patient] received regular  
(Discharge date) (Day-60)

kidney dialysis treatments outside the study hospital?-----

Yes No

If yes,

a. How many times per week?-----

--	--

b. How many miles each way did [you/patient] travel for each treatment?-----

--	--	--

 miles

c. Did someone go with [you/patient] most times?-----

Yes No

8. Between \_\_\_\_\_ and \_\_\_\_\_, have [you/patient] seen a health care  
(Discharge Date) (Day-60)

provider outside the study hospital for a reason other than your kidney problems?-----

Yes No

If yes,

a. How many times?-----

--	--

b. How many miles each way did [you/patient] travel each visit, on average?-----

--	--	--

 miles

c. Did someone go with [you/patient] most times?-----

Yes No

9. Between \_\_\_\_\_ and \_\_\_\_\_, has someone helped [you/patient]  
( Discharge Date) (Day-60)

around the house with healthcare, such as changing bandages or giving  
medications?-----

Yes No

If yes,

a. How many hours per week did someone help you with healthcare?-----

--	--	--

 hours/week

**Page 4 of 6 Instructions for Form 17N – 60 Day Follow-up for Non-VA Patients**

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

**Enter at top**

- hospital number
- patient's ID and initials

10. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

11. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

12. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)



**Page 5 of 6   Instructions for Form 17N – 60 Day Follow-up for Non-VA Patients**

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

**Enter at top**

- hospital number
- patient's ID and initials

13. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

14. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

15. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)



**Page 6 of 6 Instructions for Form 17N – 60 Day Follow-up for Non-VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**This page is for study coordinator use only:**

- 1. Mark the one box that best describes who answered the questions on the form.**
- 2. Mark 'yes' if all the questions were answered; mark 'no' otherwise. If 'no' is marked, please specify the reason in the box provided.**
- 3. Mark the one box that best indicates the main reason why the questionnaire was not completed. If 'other' is marked, please specify the reason in the space provided.**

Enter the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL (ATN STUDY)  
FORM 17N - 60 DAY FOLLOW-UP FOR NON-VA PATIENTS

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

--	--	--

FOR STUDY COORDINATOR USE ONLY

1. Who answered the questions on this form (check one)?

- Study Subject
- Someone who lives with the subject
- Someone who does not live with the subject
- No-one

2. Were all questions answered? .....  Yes  No

If No, please give reason:

--

3. If the questionnaire was not completed, indicate the main reason (check one)

- Subject deceased and no-one else was available
- Subject could not be contacted
- Subject refused to complete
- Subject could not complete due to illness or other reason and no-one else was available
- Questionnaire not administered due to institution error
- Other, specify

--

That's the end of the survey. Thank you.

Staff Initials

--	--	--

**Page 1 of 6      Instructions for Form 17V – 60 Day Follow-up for VA Patients**

**\*\*\*This form is for use by VA Sites only.**

**When to complete**

The 60<sup>th</sup> day after enrollment is called “Day 60.” Complete Form 17V on Day 60 or as soon as possible afterward. Data should be provided by the patient, or by the patient contact listed on Form 5.

Complete this form only if the patient was discharged alive from the original hospital stay. If you learn that the patient died after hospital discharge but before Day 60, you may complete the form prior to Day 60.

If the patient is well enough to give consent but has not re-consented to the study, complete only questions 1 and 2. Then send the re-consent form to the patient. You must receive it back from the patient before completing questions 3-15. You must also complete Form 2R. Remember to mail the completed Form 17V, Form 2R, and a copy of the signed re-consent form to WH CSPCC.

**Enter at top**

- hospital number (of the study hospital)
- patient’s ID and initials
- date the form was completed

**Enter in gray box**

- Discharge Date (from the hospitalization during which the patient entered the study)
- Day 60 date (or death date, if before Day 60)

1. Mark ‘yes’ if the patient has been hospitalized continuously since enrollment; mark ‘no’ otherwise.

- If ‘yes,’ you are done. Leave the remainder of the form blank.
- If ‘no,’ complete the remainder of this form.

2. Mark ‘yes’ if the patient has died; mark ‘no’ otherwise.

If the patient has died, enter the date of death in item (a) and complete the remainder of the form by asking the patient’s contact person for any needed information.

**Caution:** The patient must sign and return a re-consent form, if he/she is able, before the rest of this form may be completed.

3. Ask about inpatient hospitalizations outside the VA system between the Discharge Date and Day 60 (or death date). Mark ‘yes’ if there were any such events; mark ‘no’ otherwise and skip to question 4. If yes, enter

- a. admission date
- b. facility name
- c. facility city and state
- d. number of days the patient stayed there
- e. number of days the patient was in the ICU (for hospitalizations only)
- f. Mark ‘yes’ if there have been additional hospital admissions; mark ‘no’ otherwise. If ‘yes,’ fill in the information concerning additional hospitalizations on the continuation sheets on pages 4 and 5 of this form.



**Page 2 of 6 Instructions for Form 17V – 60 Day Follow-up for VA Patients**

**Enter at top**

- hospital number
  - patient's ID and initials
4. Ask about non-VA nursing home stays between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such events; mark 'no' otherwise and skip to question 5. If yes, enter
- a. admission date
  - b. facility name
  - c. facility city and state
  - d. number of days the patient stayed there
  - e. Mark 'yes' if there have been additional nursing home stays; mark 'no' otherwise. If 'yes,' fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.
5. Ask about hospice stays between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such events; mark 'no' otherwise and skip to question 6. If yes, enter
- a. admission date
  - b. facility name
  - c. facility city and state
  - d. number of days the patient stayed there
  - e. Mark 'yes' if there have been additional hospice stays; mark 'no' otherwise. If 'yes,' fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.



**Page 3 of 6 Instructions for Form 17V – 60 Day Follow-up for VA Patients**

**Enter at top**

- hospital number
  - patient's ID and initials
6. Ask about medical appointments between the Discharge Date and Day 60 (or death date) that were for kidney problems and occurred outside the VA system. Mark 'yes' if there were any; mark 'no' otherwise and skip to question 7.
- a. Enter the number of medical appointments the patient had for kidney problems outside of the VA system.
  - b. Enter the average number of miles traveled each way for these appointments.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
7. Ask about regular kidney dialysis treatments outside the VA system that occurred between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such treatments; mark 'no' otherwise and skip to question 8.
- a. Enter the number of times per week the patient received regular kidney dialysis treatments outside the VA system.
  - b. Enter the average number of miles traveled each way for these treatments.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
8. Ask about visits to healthcare providers outside the VA system for a reason other than kidney problems, between the Discharge Date and Day 60 (or death date). Mark 'yes' if there were any such visits; mark 'no' otherwise and skip to question 9.
- a. Enter the number of times a health care provider outside the VA system was seen for other than kidney problems.
  - b. Enter the average number of miles traveled each way for these visits.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
9. Mark 'yes' if someone helped the patient around the house with healthcare, such as changing bandages or giving medications, between the Discharge Date and Day 60 (or death date); mark 'no' otherwise. If 'yes,'
- a. Enter the number of hours per week someone helped with such healthcare.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 17V - 60 DAY FOLLOW-UP FOR VA PATIENTS

Hospital No.

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Patient ID

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Patient Initials

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Now I'd like to ask about outpatient care such as doctor appointments and visits to dialysis clinics. I'm only interested in outpatient visits outside the VA System.

6. Between \_\_\_\_\_ and \_\_\_\_\_, have [you/patient] seen a doctor  
(Discharge Date) (Day-60 date) Yes No  
outside the VA system concerning your kidney problems? -----

If Yes,

- a. How many times?----- 

--	--
- b. How many miles did [you/patient] travel each way, on average? 

--	--	--

 miles
- c. Did someone go with [you/patient] most times?-----  yes  no

7. Between \_\_\_\_\_ and \_\_\_\_\_, have [you/patient] received regular  
(Discharge Date) (Day-60 date) Yes No  
kidney dialysis treatments outside the VA system? -----

If Yes,

- a. How many times per week did they occur?----- 

--
- b. How many miles each way did [you/patient] travel for treatment? 

--	--	--

 miles
- c. Did someone go with [you/patient] most times?  yes  no

8. . Between \_\_\_\_\_ and \_\_\_\_\_, have [you/patient] made other trips for  
(Discharge Date) (Day-60 date) Yes No  
medical care outside the VA system for something other than kidney problems? -----

If Yes,

- a. How many trips?----- 

--	--
- b. How many miles each way did [you/patient] travel, on average? 

--	--	--

 miles
- c. Did someone go with [you/patient] most times?-----  yes  no

9. Between \_\_\_\_\_ and \_\_\_\_\_, has someone helped you around  
(Discharge Date) (Day-60 date) Yes No  
the house with healthcare, such as changing bandages, or giving you medications? -----

If yes,

- a. How many hours per week did someone help you with healthcare?----- 

--	--	--

 hours

**Page 4 of 6   Instructions for Form 17V – 60 Day Follow-up for VA Patients**

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

**Enter at top**

- hospital number
- patient's ID and initials

10. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

11. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

12. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)



**Page 5 of 6   Instructions for Form 17V – 60 Day Follow-up for VA Patients**

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

**Enter at top**

- hospital number
- patient's ID and initials

13. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

14. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

15. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)



**Page 6 of 6 Instructions for Form 17V – 60 Day Follow-up for VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**This page is for study coordinator use only:**

- 1. Mark the one box that best describes who answered the questions on the form.**
- 2. Mark 'yes' if all the questions were answered; mark 'no' otherwise. If 'no' is marked, please specify the reason in the box provided.**
- 3. Mark the one box that indicates the main reason why the questionnaire was not completed. If 'other' is marked, please specify the reason in the space provided.**

Enter the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 17V - 60 DAY FOLLOW-UP FOR VA PATIENTS

Hospital No.

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Patient ID

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Patient Initials

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FOR STUDY COORDINATOR USE ONLY

1. Who answered the questions on this form (choose one)?

- Study Subject
- Someone who lives with the subject
- Someone who does not live with the subject
- No-one

2. Were all questions answered? -----  Yes  No

If No, please give reason:

--

3. If the questionnaire was not completed, indicate the main reason (check one)

- Subject deceased and no-one else was available
- Subject could not be contacted
- Subject refused to complete
- Subject could not complete due to illness or other reason and no-one else was available
- Questionnaire not administered due to institution error
- Other, specify

--

That's the end of the survey. Thank you.

Staff Initials

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**S. Instructions for Form 18N – 12-Month Follow-up for Non-VA Patients**

**\*\*\*This form is for use by Hospitals number 901 through 910 only.**

**When to complete**

Complete this form only if the patient was alive at Day 60. The 12-month follow-up should occur at approximately the 365<sup>th</sup> day after enrollment (“Day 365”). If you learn that the patient died after Day 60 but before Day 365, you may complete the form prior to Day 365. Otherwise, complete Form 18N as soon as possible after Day 365.

Data should be provided by the patient, or by the patient contact listed on Form 5. You will be asking about events since Day 60 (see Form 17N).

If the patient is well enough to give consent but has not re-consented to the study, complete only questions 1 and 2. Then send the re-consent form to the patient. You must receive it back from the patient before completing questions 3-15. You must also complete form 2R. Remember to send the completed Form 18N, Form 2R, and the signed re-consent form to WH CSPCC.

**Enter at top**

- hospital number (of the study hospital).
- patient’s ID and initials.
- date the form was completed.

**Enter in gray box**

- Day 60 date

1. Mark ‘yes’ if the patient has died; mark ‘no’ otherwise.

If the patient has died, enter the date of death in item (a) and complete the remainder of the form by asking the patient’s contact person for any needed information.

**Caution:** The patient must sign and return a re-consent form, if he/she is able, before the rest of this form may be completed. If the patient signed and returned a re-consent form earlier, that is sufficient.

2. Ask about inpatient hospitalizations outside the study hospital since Day 60. Mark ‘yes’ if there were any such events; mark ‘no’ otherwise and skip to question 3. If ‘yes’, enter
  - a. admission date.
  - b. facility name.
  - c. facility city and state.
  - d. number of days the patient stayed there.
  - e. number of days the patient was in the ICU (for hospitalizations only).
  - f. Mark ‘yes’ if there have been additional hospital admissions; mark ‘no’ otherwise. If ‘yes,’ fill in the information concerning additional hospitalizations on the continuation sheets on pages 4 and 5 of this form.



**Instructions for Form 18N – 12-Month Follow-up for Non-VA Patients**

**Enter at top**

- hospital number
  - patient's ID and initials
- 
3. Ask about nursing home stays since the Day 60. Mark 'yes' if there were any such events; mark 'no' otherwise and skip to question 4. If 'yes', enter
    - a. admission date.
    - b. facility name.
    - c. facility city and state.
    - d. number of days the patient stayed there.
    - e. Mark 'yes' if there have been additional nursing home stays; mark 'no' otherwise. If 'yes,' fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.
  
  4. Ask about hospice stays since Day 60. Mark 'yes' if there were any such events; mark 'no' otherwise and skip to question 5. If yes, enter
    - a. admission date.
    - b. facility name.
    - c. facility city and state.
    - d. number of days the patient stayed there.
    - e. Mark 'yes' if there have been additional hospice stays; mark 'no' otherwise. If 'yes,' fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.



**Instructions for Form 18N – 12-Month Follow-up for Non-VA Patients**

**Enter at top**

- hospital number.
  - patient's ID and initials.
5. Ask about medical appointments since Day 60 that were for kidney problems and occurred outside the study hospital. Mark 'yes' if there were any; mark 'no' otherwise and skip to question 6.
    - a. Enter the number of medical appointments the patient had for kidney problems outside of the study hospital.
    - b. Enter the average number of miles traveled each way for these appointments.
    - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
  6. Ask about regular kidney dialysis treatments outside the study hospital that occurred since Day 60. Mark 'yes' if there were any such treatments; mark 'no' otherwise and skip to question 7.
    - a. Enter the number of times per week the patient received regular kidney dialysis treatments outside the study hospital.
    - b. Enter the average number of miles traveled each way for these treatments.
    - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
  7. Ask about visits to healthcare providers outside the study hospital for a reason other than kidney problems, since Day 60. Mark 'yes' if there were any such visits; mark 'no' otherwise and skip to question 8.
    - a. Enter the number of times a health care provider outside the study hospital was seen for other than kidney problems.
    - b. Enter the average number of miles traveled each way for these visits.
    - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
  8. Mark 'yes' if someone helped the patient around the house with healthcare, such as changing bandages or giving medications, since Day 60; mark 'no' otherwise. If 'yes,'
    - a. Enter the number of hours per week someone helped with such healthcare.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 18N - 12 MONTH FOLLOW-UP FOR NON-VA PATIENTS

Hospital No.

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Patient ID

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Patient Initials

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Now I'd like to ask about outpatient care, such as doctor appointments and visits to kidney dialysis clinics.

5. Since \_\_\_\_\_, have [you/patient] had any medical appointments outside the study  
(60-day survey date) Yes  No   
hospital concerning kidney problems? -----

If Yes,

- a. How many medical appointments? ----- 

--	--
- b. How many miles each way did [you/patient] travel on average? 

--	--	--

 miles
- c. Did someone go with [you/patient] most times?  yes  no

6. Since \_\_\_\_\_, have [you/patient] received regular kidney dialysis  
(60-day survey date) Yes  No   
treatments outside the study hospital? -----

If Yes,

- a. How many times per week? ----- 

--
- b. How many miles each way did [you/patient] travel for treatment? 

--	--	--

 miles
- c. Did someone go with [you/patient] most times?  yes  no

7. Since \_\_\_\_\_, have [you/patient] had any medical appointment outside  
(60-day survey date) Yes  No   
the hospital for something other than kidney problems? -----

If Yes,

- a. How many times? ----- 

--	--
- b. How many miles each way did [you/patient] travel, on average. 

--	--	--

 miles
- c. Did someone go with [you/patient] most times? -----  yes  no

8. In the last week, has someone helped [you/patient] around the house with healthcare, such as  
changing bandages or giving medications? ----- Yes  No

If Yes,

- a. How many hours did someone help with healthcare last week? ----- 

--	--	--

 hours

**Instructions for Form 18N – 12-Month Follow-up for Non-VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

9. Check one box to indicate the type of admission. Enter the following:
  - a. the admission date
  - b. the name of the facility
  - c. the city and state where the facility is located
  - d. the number of days the patient was in that facility
  - e. the number of days in the ICU (for hospitalizations only)
  
10. Check one box to indicate the type of admission. Enter the following:
  - a. the admission date
  - b. the name of the facility
  - c. the city and state where the facility is located
  - d. the number of days the patient was in that facility
  - e. the number of days in the ICU (for hospitalizations only)
  
11. Check one box to indicate the type of admission. Enter the following:
  - a. the admission date
  - b. the name of the facility
  - c. the city and state where the facility is located
  - d. the number of days the patient was in that facility
  - e. the number of days in the ICU (for hospitalizations only)



**Instructions for Form 18N – 12-Month Follow-up for Non-VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

12. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

13. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

14. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)



**Instructions for Form 18N – 12-Month Follow-up for Non-VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**This page is for study coordinator use only:**

1. Mark the one box that best describes who answered the questions on this form.
2. Mark 'yes' if all the questions were answered; mark 'no' otherwise. If 'no' is marked, please give the reason in the box provided.
3. Mark the one box that indicates the main reason why the questionnaire was not completed. If 'other' is marked, please specify the reason in the space provided.

Enter the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 18N - 12 MONTH FOLLOW-UP FOR NON-VA PATIENTS

Hospital No.

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Patient ID

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Patient Initials

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FOR STUDY COORDINATOR USE ONLY

1. Who answered the questions on this form (check one)?

- Study Subject
- Someone who lives with the subject
- Someone who does not live with the subject
- No-one

2. Were all questions answered? .....  Yes  No

If No, please give reason:

--

3. If the questionnaire was not completed, indicate the main reason (check one)

- Subject deceased and no-one else was available
- Subject could not be contacted
- Subject refused to complete
- Subject could not complete due to illness or other reason and no-one else was available
- Questionnaire not administered due to institution error
- Other, specify

--

That's the end of the survey. Thank you.

Staff Initials

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**Instructions for Form 18V – 12-Month Follow-up for VA Patients**

\*\*\*This form is for use by VA Sites only.

**When to complete**

Complete this form only if the patient was alive at Day 60. The 12-month follow-up should occur at approximately the 365<sup>th</sup> day after enrollment (“Day 365”). If you learn that the patient died after Day 60 but before Day 365, you may complete the form prior to Day 365. Otherwise, complete Form 18V as soon as possible after Day 365.

**Who provides the information:** Data should be provided by the patient, or by the patient contact listed on Form 5. You will be asking about events since Day 60 (see Form 17V).

**Note:** If the patient is well enough to give consent but has not re-consented to the study, complete only questions 1 and 2. Then send the re-consent form to the patient. You must receive it back from the patient before completing questions 3-15. You must also complete Form 2R. Remember to send the completed Form 18V, Form 2R, and a copy of the signed re-consent form to WH CSPCC.

**Enter at top**

- hospital number (of the study hospital)
- patient’s ID and initials
- date the form was completed

**Enter in gray box** – The Day 60 date.

1. Mark ‘yes’ if the patient has died; mark ‘no’ otherwise.  
If the patient has died, enter the date of death in item (a) and complete the remainder of the form by asking the patient’s contact person for any needed information.  
**Caution:** The patient must sign and return a re-consent form, if he/she is able, before the rest of this form may be completed. If the patient signed and returned a re-consent form earlier, that is sufficient.
2. Ask about inpatient hospitalizations outside the VA system since Day 60. Mark ‘yes’ if there were any such events; mark ‘no’ otherwise and skip to question 3. If yes,
  - a. admission date
  - b. facility name
  - c. facility city and state
  - d. number of days the patient stayed there
  - e. number of days the patient was in the ICU (for hospitalizations only)
  - f. Mark ‘yes’ if there have been additional hospital admissions; mark ‘no’ otherwise. If ‘yes,’ fill in the information concerning additional hospitalizations on the continuation sheets on pages 4 and 5 of this form.
3. Ask about nursing home stays since the Day 60. Mark ‘yes’ if there were any such events; mark ‘no’ otherwise and skip to question 4. If yes, enter
  - a. admission date
  - b. facility name
  - c. facility city and state
  - d. number of days the patient stayed there
  - e. Mark ‘yes’ if there have been additional nursing home stays; mark ‘no’ otherwise. If ‘yes,’ fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 18V - 12 MONTH FOLLOW-UP FOR VA PATIENTS

Hospital No.

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Patient ID

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Patient Initials

--	--	--

Date Form Completed

		/			/		
--	--	---	--	--	---	--	--

Yes No

1. Has the patient died?.....

If Yes,

a. Date of Death

		/			/		
--	--	---	--	--	---	--	--

 (mm/dd/yy)

I am going to read you a list of questions about medical care that [you/patient] may have received outside of the VA system. I am only interested in care you received since \_\_\_\_\_, the date of the last survey. (60-Day survey date)

2. Since \_\_\_\_\_, were [you/patient] admitted to any hospital outside the VA System?  
(60-day survey date)

Yes No

If Yes,

a. Admission date: .....

		/			/		
--	--	---	--	--	---	--	--

 (mm/dd/yy)

b. Facility name:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

c. City and state where facility located:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

d. How many days did [you/patient] stay in that hospital?.....

--	--	--

 Days

e. How many days were [you/patient] in the Intensive Care Unit?.....

--	--	--

 Days

f. Have there been additional admissions?.....  yes  no

If Yes, use the continuation sheets on pages 4 and 5 to record additional hospital admissions.

3. Since \_\_\_\_\_, were [you/patient] admitted to any nursing home outside the VA System?  
(60-day survey date)

Yes No

If Yes,

a. Admission date: .....

		/			/		
--	--	---	--	--	---	--	--

 (mm/dd/yy)

b. Facility name:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

c. City and state where facility located:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

d. How many days were [you/patient] in the nursing home?.....

--	--	--

 Days

e. Have there been additional nursing home admissions?.....  yes  no

If Yes, use the continuation sheets on pages 4 and 5 to record additional nursing home admissions.

**Instructions for Form 18V – 12-Month Follow-up for VA Patients**

**Enter at top**

- hospital number
  - patient's ID and initials
4. Ask about hospice stays since Day 60. Mark 'yes' if there were any such events; mark 'no' otherwise and skip to question 5. If yes, enter
- a. admission date
  - b. facility name
  - c. facility city and state
  - d. number of days the patient stayed there
  - e. Mark 'yes' if there have been additional hospice stays; mark 'no' otherwise. If 'yes,' fill in the information concerning additional stays on the continuation sheets on pages 4 and 5 of this form.
5. Ask about medical appointments since Day 60 that were for kidney problems and occurred outside the VA system. Mark 'yes' if there were any; mark 'no' otherwise and skip to question 6.
- a. Enter the number of medical appointments the patient had for kidney problems outside of the VA system.
  - b. Enter the average number of miles traveled each way for these appointments.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
6. Ask about regular kidney dialysis treatments outside the VA system that occurred since Day 60. Mark 'yes' if there were any such treatments; mark 'no' otherwise and skip to question 7.
- a. Enter the number of times per week the patient received regular kidney dialysis treatments outside the VA system.
  - b. Enter the average number of miles traveled each way for these treatments.
  - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.



**Instructions for Form 18V – 12-Month Follow-up for VA Patients**

**Enter at top**

- hospital number
  - patient's ID and initials
- 
7. Ask about visits to healthcare providers outside the VA system for a reason other than kidney problems, since Day 60. Mark 'yes' if there were any such visits; mark 'no' otherwise and skip to question 8.
    - a. Enter the number of times a health care provider outside the VA system was seen for other than kidney problems.
    - b. Enter the average number of miles traveled each way for these visits.
    - c. Mark 'yes' if someone went to these appointments with the patient most of the time; mark 'no' otherwise.
  
  8. Mark 'yes' if someone helped the patient around the house with healthcare, such as changing bandages or giving medications, since Day 60; mark 'no' otherwise. If 'yes,'
    - a. Enter the number of hours per week someone helped with such healthcare.
  
  9. Ask whether the patient has filled a prescription at a non-VA pharmacy since Day 60. If so, mark 'yes'; mark 'no' otherwise. If 'yes,'
    - a. Enter the number of prescriptions.

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

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7. Since \_\_\_\_\_, have [you/patient] had medical appointments outside the VA System  
(60-day survey date) Yes  No   
for something other than kidney problems.....

If Yes,

- a. How many visits? ..... 

--	--
- b. How many miles each way did [you/patient] travel, on average? 

--	--	--

 miles
- c. Did someone go with [you/patient] most times?.....  yes  no

8. In the last week has someone helped [you/patient] around the house with healthcare,  
such as changing bandages or giving you medication?..... Yes  No

If yes,

- a. How many hours did someone help you with healthcare last week? 

--	--	--

 hours

Now I'd like to ask you about prescription medications.

9. Since \_\_\_\_\_, have you obtained a prescription at any pharmacy other than a  
(60-day survey date) Yes  No   
VA pharmacy.....

If yes,

- a. About how many prescriptions was that? ..... 

--	--

**Instructions for Form 18V – 12-Month Follow-up for VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

10. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

11. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

12. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 18V - 12 MONTH FOLLOW-UP FOR VA PATIENTS

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

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USE THIS PAGE TO RECORD ADDITIONAL ADMISSIONS TO HOSPITALS, NURSING HOMES, OR HOSPICE.

10. Type (check one):  hospital  nursing home  hospice

a. Admission date: 

--	--

 / 

--	--

 / 

--	--

 (mm/dd/yy)

b. Facility name

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c. City and state where facility located:

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d. How many days were [you/patient] there?

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 days

e. For hospital stays, how many days were spent in an Intensive Care Unit?

--	--

 days

11. Type (check one):  hospital  nursing home  hospice

a. Admission date: 

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 (mm/dd/yy)

b. Facility name

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c. City and state where facility located:

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d. How many days were [you/patient] there?

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 days

e. For hospital stays, how many days were spent in an Intensive Care Unit?

--	--

 days

12. Type (check one):  hospital  nursing home  hospice

a. Admission date: 

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 / 

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 (mm/dd/yy)

b. Facility name

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c. City and state where facility located:

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d. How many days were [you/patient] there?

--	--

 days

e. For hospital stays, how many days were spent in an Intensive Care Unit?

--	--

 days

**Instructions for Form 18V – 12-Month Follow-up for VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**Use this page to record additional admissions to hospitals, nursing homes, or hospices.**

13. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

14. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)

15. Check one box to indicate the type of admission. Enter the following:

- a. the admission date
- b. the name of the facility
- c. the city and state where the facility is located
- d. the number of days the patient was in that facility
- e. the number of days in the ICU (for hospitalizations only)



**Instructions for Form 18V – 12-Month Follow-up for VA Patients**

**Enter at top**

- hospital number
- patient's ID and initials

**This page is for study coordinator use only:**

1. Mark the one box that best describes who answered the questions on this form.
2. Mark 'yes' if all the questions were answered; mark 'no' otherwise. If 'no' is marked please specify the reason in the box provided.
3. Mark the one box that indicates the main reason why the questionnaire was not completed. If 'other' is marked, please specify the reason in the box provided.

Enter the initials of the staff member completing this form.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 18V - 12 MONTH FOLLOW-UP FOR VA PATIENTS

Hospital No.

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Patient ID

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Patient Initials

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FOR STUDY COORDINATOR USE ONLY

1. Who answered the questions on this form (check one)?

- Study Subject
- Someone who lives with the subject
- Someone who does not live with the subject
- No-one

2. Were all questions answered? -----  Yes  No

If No, please give reason:

--

3. If the questionnaire was not completed, indicate the main reason (check one)

- Subject deceased and no-one else was available
- Subject could not be contacted
- Subject refused to complete
- Subject could not complete due to illness or other reason and no-one else was available
- Questionnaire not administered due to institution error
- Other, specify

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That's the end of the survey. Thank you.

Staff Initials

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## **T. Forms 19 – General Instructions for the Administration of the HUI**

This section presents guidelines for administering the Health Utilities Index (Forms 19S and 19P). This form is to be administered to the subject over the phone at 60 days and one year after study enrollment, at the same time that the phone surveys (17N or 17V and 18N or 18V) are administered.

It is important that the questionnaire administrator establishes a rapport with the subject and encourages the subject to answer all the questions on the form. Subjects are more likely to answer the questions honestly and completely if they have a positive impression or relationship with the administrator. The administrator can emphasize to subjects the importance of their answers to the completion of the study as well as answer questions and address concerns about the HUI to help ensure that the questions are answered correctly and completely. Guidelines for how to address common questions and concerns are listed below.

### **Introducing the HUI**

The following script (or a variation appropriately reworded to sound more like your style of speech) is suggested for introducing the Health Utilities Index:

*“We would like to better understand how you and other subjects in this study feel, how well you are able to do your usual activities, and how you rate your own health. To help us better understand these things about you, please answer the following questions about your general health.”*

Read the instructions on page one of the HUI to the subject. After the completion of the form, thank the subject.

### **Addressing Problems and Questions**

#### ***What should I do if the subject refuses to answer the questions on the HUI?***

Tell the subject that completion of the questionnaire is voluntary, but that it will provide important information about treatment of Acute Renal Failure. Emphasize that this information is as important as any of the other medical information. The questionnaire responses are essential in order to get a complete picture of the subject's health. Emphasize that the questions will be easy to answer. Suggest that it is possible that this questionnaire is different from others they have completed in the past, and that they may even enjoy completing this questionnaire. If the subject still refuses, record the reason for refusal in the progress notes and on the form, and thank the subject.

#### ***What if a subject refuses to complete the HUI?***

1. Ask: Does the patient understand the question being asked?
  - Yes: Offer to reread the question, but do not attempt to explain it. If the patient gives an answer, continue with the survey.
  - No: See 2, below.
2. Ask: Is there someone who can assist the subject in completing the form, such as a spouse, relative, or friend?

- Yes: Allow that person to help the subject; reschedule if necessary. If the subject is unable to complete the form even with assistance, see 3 below.
- No: See 4, below.
3. Ask: is there someone (a proxy) who can complete the form on the subject's behalf, such as a spouse, relative, or friend? This should be someone who spends time with the subject most days of the week.
- Yes: Have the proxy complete Form 19P (not 19S). Then send both the incomplete Form 19S and the completed Form 19P to the West Haven CSPCC, with a note explaining that the subject was unable to complete the form, the reason for non-completion, and the relation of the proxy to the subject.
- No: See 4, below.
4. Send the incomplete Form 19S to the West Haven CSPCC with a note explaining that the subject was unable to complete the form, the reason for non-completion, and that there was no proxy available to complete Form 19P.

***What should I do if the subject asks for clarification of an item?***

While completing the questionnaire, some subjects might ask for clarification of *specific items* so that they can better understand and respond to a question. If this happens, the staff member can assist the subject by rereading the question for them. If the subject asks what something means, do not try to explain what the question means, but suggest that the subject use his or her own interpretation of the question. All subjects should answer the questions based on what they think the questions mean.

Sometimes subjects may have trouble with the response choices. They may say "I don't know" or something different than what is stated on the questionnaire. In these circumstances it is important to gently guide the subject to respond in one of the pre-set categories by saying something like:

*"I know that it may be hard for you to think this way, but which of these categories most closely expresses what you are thinking or feeling"?*

It is possible that subjects may ask if certain items, particularly the pain items, are limited to a specific health problem. Explain to the subject that these questions ask about their health in general.

If the subject does not like a question, or thinks it is unnecessary or inappropriate, emphasize that all questions are in the survey for a reason that is very important to the study and, if possible, the subject should try to answer all of the questions. However, the completion of any question is completely voluntary.

Differences in answers due to different wordings of the questionnaire can bias results. It is important to minimize these differences. If the subject has repeated difficulties completing the questionnaire, which you cannot address with the above direction, thank the subject, and record the difficulty on the form.

***What should I do if a subject wants to know what his/her answers mean?***

If a subject asks for interpretation of their responses or asks for their score on the questionnaire, tell subjects that you are not trained in how to score or interpret the questionnaire.

***What should I do if a subject is concerned someone will see their answers?***

Emphasize that all subjects' responses to the questionnaires will be kept confidential. You are not allowed to read the responses other than to check that all responses are answered. Point out that the ID number is used to identify a subject and that the results will be linked with this number and not their name. In addition, explain that their answers to the questionnaire will be pooled with other subjects' answers and that they will be analyzed as a group rather than as individuals for the study.

***What should I do if a subject asks why the questionnaires must be filled out more than once?***

Explain that subjects are surveyed at 60 days and one year following their enrollment in the ATN study in order to see if their answers change over time. This will give us a more complete picture of the subject's health over the course of time.

**Administration of the HUI: DOs and DON'Ts**

<b>DOs</b>	<b>DON'Ts</b>
Do be warm, friendly, and helpful	Do not force or command subjects to answer the questions in the HUI.
Do request and encourage subjects to answer all questions on the HUI	Do not accept an incomplete questionnaire without first encouraging the subject answer all questions
Do read and repeat a question verbatim for the subject	Do not interpret or explain a question
Do tell subjects to answer a question based on what they think the question means	Do not force or command subjects to fill out a particular question
Do encourage subjects to answer the questions by themselves or ask someone else present to help	Do not refuse to allow spouses or family members to help the subject answer the questions
Do encourage subjects to answer all questions	Do not minimize the importance of the questionnaire
Do thank subjects for answering the questions	
Do inform subjects that they will be contacted again approximately one year after enrollment in the ATN study to complete the same questionnaire again	

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**Instructions for Form 19P – Health Utility Index (HUI) Form-Administered to a Proxy for the Study Subject**

**Enter Hospital Number, Patient ID, Patient Initials, and the Date Form Completed at the top of every page of the form.**

**When to complete this form:** This form must be completed twice for every subject: (1) at study day 60 [where study day 1 is the day the subject was randomized into the study], and (2) at 12 months after enrollment into the study. Administer the form over the telephone.

**Who should complete the form:** The form should be administered to the study subject if at all possible. If administering the form to the study subject, you must use Form 19S. Only administer the form to a proxy if the subject will be unable to answer questions for the foreseeable future. The proxy should be someone, such as a spouse, who has spent considerable time in the past week assisting the subject with many aspects of daily life.

**Consistency:** If a proxy completed the form at 60 days, both that same proxy and the patient (if possible) should complete the form at 12 months. If at all possible, avoid having different proxies complete the form at 60 days and at 12 months. This means that you must keep a record of who completed the form at the 60 day time period.

- A. **ADMINISTRATION TIME PERIOD:** Mark the one box that indicates the time period at which this interview is being conducted.
- B. Read aloud the instructions at the top of the shaded area on the first page.
- C. Follow the instructions at the bottom of the shaded area on the first page when conducting the interview.
- D. On the last page, the coordinator must complete items 1, 2, and 3.
  - 1. Mark the one box that tells who answered the questions in this questionnaire.
  - 2. Mark ‘yes’ if all the questions were answered; otherwise mark ‘no’. If ‘no’ is marked, specify the reason in the box provided.
  - 3. Mark the one box that best indicates the main reason why the questionnaire was not complete. If ‘other’ is marked, please specify the reason in the box provided.
- E. At the bottom of the last page, enter the initials of the staff member who conducted the interview.

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

		/			/		
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ADMINISTRATION TIME PERIOD (check one box only)     60 Days     12 Months

INTERVIEWER-ADMINISTERED, PROXY-ASSESSED  
"ONE-WEEK" HEALTH STATUS ASSESSMENT

The next set of questions ask about various aspects of your health. When answering these questions we would like you to think about (his/her) health and your ability to do things on a day-to-day basis, during the past week. To define the past week period, please think about what the date was 7 days ago and recall the major events that (he/she) have experienced during this period. Please focus your answers on (subject's name) abilities, disabilities and how you have felt during the past week. You may feel that some of these questions do not apply to (subject's name), but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about (subject's name) abilities and feelings.

## Interviewer:

For each question, read the entire sentence as written on the left-hand side of the page following the question number, emphasizing the words in italics, if any. Do not read the response options listed down the right-hand margin of the page. The answer given by the respondent to each question should be clearly marked beside the one appropriate code listed to the right side of the question.

## VISION

- |                                                                                                                                                 |                                                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1. During the past week, has (subject's name) been able to see well enough to read ordinary newspaper without glasses or contact lenses?</p> | <p><input type="radio"/> Yes → Go to 4<br/> <input type="radio"/> No<br/> <input type="radio"/> Don't know<br/> <input type="radio"/> Refused</p>                                       |
| <p>2. Has (subject's name) been able to see well enough to read ordinary newspaper with glasses or contact lenses?</p>                          | <p><input type="radio"/> Yes → Go to 4<br/> <input type="radio"/> No<br/> <input type="radio"/> Don't know/Didn't wear glasses or contact lenses<br/> <input type="radio"/> Refused</p> |

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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3. During the past week, has (subject's name) been able to see at all?

- Yes  
 No → Go to 6  
 Don't know  
 Refused

4. During the past week, has (subject's name) been able to see well enough to recognize a friend on the other side of the street without glasses or contact lenses?

- Yes → Go to 6  
 No  
 Don't know  
 Refused

5. Has (subject's name) been able to see well enough to recognize a friend on the other side of the street with glasses or contact lenses?

- Yes  
 No  
 Don't know/Didn't wear glasses or contact lenses  
 Refused

## HEARING

6. During the past week, has (subject's name) been able to hear what is said in a group conversation with at least three other people without a hearing aid?

- Yes → Go to 11  
 No  
 Don't know  
 Refused

7. Has (subject's name) been able to hear what is said in a group conversation with at least three other people with a hearing aid?

- Yes → Go to 9  
 No  
 Don't know/Didn't wear a hearing aid  
 Refused

8. During the past week, has (subject's name) been able to hear at all?

- Yes  
 No → Go to 11  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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9. During the past week, has (subject's name) you been able to hear what is said in a conversation with one other person in a quiet room without a hearing aid?
- Yes → Go to 11  
 No  
 Don't know  
 Refused
10. Has (subject's name) been able to hear what is said in a conversation with one other person in a quiet room with a hearing aid?
- Yes  
 No  
 Don't know/Didn't wear a hearing aid  
 Refused

### SPEECH

11. During the past week, has (subject's name) been able to be understood completely when speaking (subject's name) own language with people who do not know you?
- Yes -> Go to 16  
 No  
 Don't know  
 Refused
12. Has (subject's name) been able to be understood partially when speaking with people who do not know (subject's name)?
- Yes  
 No  
 Don't know  
 Refused
13. During the past week, has (subject's name) been able to be understood completely when speaking with people who know (subject's name) well?
- Yes -> Go to 16  
 No  
 Don't know  
 Refused
14. Has (subject's name) been able to be understood partially when speaking with people who know (subject's name) well?
- Yes -> Go to 16  
 No  
 Don't know  
 Refused
15. During the past week has (subject's name) been able to speak at all?
- Yes  
 No  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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## GETTING AROUND

16. During the past week, has (subject's name) been able to bend, lift, jump and run without difficulty and without help or equipment of any kind?
- Yes -> Go to 24  
 No  
 Don't know  
 Refused
17. Has (subject's name) been able to walk around the neighborhood without difficulty and without help or equipment of any kind?
- Yes -> Go to 24  
 No  
 Don't know  
 Refused
18. Has (subject's name) been able to walk around the neighborhood with difficulty but without help or equipment of any kind?
- Yes -> Go to 24  
 No  
 Don't know  
 Refused
19. During the past week, has (subject's name) you been able to walk at all?
- Yes  
 No -> Go to 22  
 Don't know  
 Refused
20. Has (subject's name) needed mechanical support, such as braces or a cane or crutches, to be able to walk around the neighborhood?
- Yes  
 No  
 Don't know  
 Refused
21. Has (subject's name) you needed the help of another person to walk?
- Yes  
 No  
 Don't know  
 Refused
22. Has (subject's name) needed a wheelchair to get around the neighborhood?
- Yes  
 No  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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23. Has (subject's name) needed the help of another person to get around in the wheelchair?

- Yes  
 No  
 Don't know  
 Refused

#### HANDS AND FINGERS

24. During the past week, has (subject's name) had the full use of both hands and ten fingers?

- Yes -> Go to 28  
 No  
 Don't know  
 Refused

25. Has (subject's name) needed the help of another person because of limitations in the use of your hands or fingers?

- Yes  
 No -> Go to 27  
 Don't know  
 Refused

26. Has (subject's name) needed the help of another person with some tasks, most tasks, or all tasks?

- Some tasks  
 Most tasks  
 All tasks  
 Don't know  
 Refused

27. Has (subject's name) needed special equipment, for example special tools to help with dressing or eating, because of limitations in the use of his/her hands or fingers?

- Yes  
 No  
 Don't know  
 Refused

#### SELF-CARE

28. During the past week, has (subject's name) been able to eat, bathe, dress and use the toilet without difficulty?

- Yes -> Go to 31  
 No  
 Don't know  
 Refused

29. Has (subject's name) needed the help of another person to eat, bathe, dress or use the toilet?

- Yes  
 No  
 Don't know  
 Refused

30. Has (subject's name) needed special equipment or tools to eat, bathe, dress and use the toilet?

- Yes  
 No  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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## FEELINGS

31. During the past week, has (subject's name) been feeling happy or unhappy?
- Happy
  - Unhappy -> Go to 33
  - Don't know
  - Refused
32. Would you describe (subject's name) as having felt:
- a) happy and interested in life, or
  - b) somewhat happy?
- a -> Go to 34
  - b -> Go to 34
  - Don't know
  - Refused
33. Would you describe (subject's name) as having felt:
- a) somewhat unhappy
  - b) very unhappy
  - c) so unhappy that life was not worthwhile
- a
  - b
  - c
  - Don't know
  - Refused
34. During the past week did (subject's name) ever feel fretful, angry, irritable, anxious or depressed?
- Yes
  - No -> Go to 37
  - Don't know
  - Refused
35. How often did (subject's name) feel fretful, angry, irritable, anxious or depressed: rarely, occasionally, often, or almost always?
- Rarely
  - Occasionally
  - Often
  - Almost always
  - Don't know
  - Refused
36. During the past week did (subject's name) feel extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help?
- Yes
  - No
  - Don't know
  - Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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**MEMORY**

37. How would you describe (subject's name) ability to remember things, during the past week:
- (a) able to remember most things  a
- (b) somewhat forgetful  b
- (c) very forgetful  c
- (d) unable to remember anything at all?  d
- Don't know
- Refused

**THINKING**

38. How would you describe (subject's name) ability to think and solve day to day problems, during the past week:
- (a) able to think clearly and solve problems  a
- (b) had a little difficulty  b
- (c) had some difficulty  c
- (d) had a great deal of difficulty  d
- (e) unable to think or solve problems?  e
- Don't know
- Refused

**PAIN AND DISCOMFORT**

39. Has (subject's name) had any trouble with pain or discomfort, during the past week?
- Yes
- No -> Go to 41
- Don't know
- Refused
40. How many of (subject's name) activities, during the past week, were limited by pain or discomfort: none, a few, some, most, all?
- None
- A few
- Some
- Most
- Don't know
- Refused
41. Overall, how would you rate (subject's name) health during the past week?
- (a) excellent  a
- (b) very good  b
- (c) good  c
- (d) fair  d
- (e) poor  e
- Don't know
- Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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FOR STUDY COORDINATOR USE ONLY

1. Who answered the questions on this form (check one)?

- Study Subject
- Someone who lives with the subject
- Someone who does not live with the subject
- No-one

2. Were all questions answered? .....  Yes  No

If No, please give reason:

--

3. If the questionnaire was not completed, indicate the main reason (check one)

- Subject deceased and no-one else was available
- Subject could not be contacted
- Subject refused to complete
- Subject could not complete due to illness or other reason and no-one else was available
- Questionnaire not administered due to institution error
- Other, specify

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That's the end of the survey. Thank you.

Staff Initials

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**Instructions for Form 19S – Health Utility Index (HUI) Form-Administered to Study Subject**

**Enter Hospital Number, Patient ID, Patient Initials, and the Date Form Completed at the top of every page of the form.**

**When to complete this form:** This form must be completed twice for every subject: (1) at study day 60, remembering that study day 1 is the day the subject was randomized into the study, and (2) at 12 months after enrollment into the study. Administer the form over the phone.

**Who should complete this form:** The form should be administered to the study subject if at all possible. If a proxy completed the form (Form 19P) at 60 days, both that same proxy and the patient (if possible) should complete the form at 12 months. Use Form 19P for the proxy and Form 19S for the study subject.

- A. **ADMINISTRATION TIME PERIOD:** Mark the one box that indicates the time period at which this interview is being conducted.
- B. Read aloud the instructions at the top of the shaded area on the first page.
- C. Follow the instructions at the bottom part of the shaded area on the first page.
- D. On the last page, the coordinator must complete items 1, 2, and 3.
  - 1. Mark the one box that tells who answered the questions in this questionnaire.
  - 2. Mark 'yes' if all the questions were answered; otherwise mark 'no'. If 'no' is marked, specify the reason in the box provided.
  - 3. Mark the one box that best indicates the main reason why the questionnaire was not completed. If 'other' is marked, please specify the reason in the box provided.
- E. At the bottom of the last page, enter the initials of the staff member who conducted the interview.

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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ADMINISTRATION TIME PERIOD (check one box only)     60 Days     12 Months

INTERVIEWER-ADMINISTERED, SELF-ASSESSED  
"ONE-WEEK" HEALTH STATUS ASSESSMENT

The next set of questions ask about various aspects of your health. When answering these questions we would like you to think about your health and your ability to do things on a day-to-day basis, during the past week. To define the past week period, please think about what the date was 7 days ago and recall the major events that you have experienced during this period. Please focus your answers on your abilities, disabilities and how you have felt during the past week. You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.

## Interviewer:

For each question, read the entire sentence as written on the left-hand side of the page following the question number, emphasizing the words in italics, if any. Do not read the response options listed down the right-hand margin of the page. The answer given by the respondent to each question should be clearly marked beside the one appropriate code listed to the right side of the question.

## VISION

1. During the past week, have you been able to see well enough to read ordinary newsprint without glasses or contact lenses?
  - Yes → Go to 4
  - No
  - Don't know
  - Refused
  
2. Have you been able to see well enough to read ordinary newsprint with glasses or contact lenses?
  - Yes → Go to 4
  - No
  - Don't know/Didn't wear glasses or contact lenses
  - Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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3. During the past week, have you been able to see at all?

- Yes  
 No → Go to 6  
 Don't know  
 Refused

4. During the past week, have you been able to see well enough to recognize a friend on the other side of the street without glasses or contact lenses?

- Yes → Go to 6  
 No  
 Don't know  
 Refused

5. Have you been able to see well enough to recognize a friend on the other side of the street with glasses or contact lenses?

- Yes  
 No  
 Don't know/Didn't wear glasses or contact lenses  
 Refused

#### HEARING

6. During the past week, have you been able to hear what is said in a group conversation with at least three other people without a hearing aid?

- Yes → Go to 11  
 No  
 Don't know  
 Refused

7. Have you been able to hear what is said in a group conversation with at least three other people with a hearing aid?

- Yes → Go to 9  
 No  
 Don't know/Didn't wear a hearing aid  
 Refused

8. During the past week, have you been able to hear at all?

- Yes  
 No → Go to 11  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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9. During the past week, have you been able to hear what is said in a conversation with one other person in a quiet room without a hearing aid?
- Yes → Go to 11  
 No  
 Don't know  
 Refused
10. Have you been able to hear what is said in a conversation with one other person in a quiet room with a hearing aid?
- Yes  
 No  
 Don't know/Didn't wear a hearing aid  
 Refused

### SPEECH

11. During the past week, have you been able to be understood completely when speaking your own language with people who do not know you?
- Yes -> Go to 16  
 No  
 Don't know  
 Refused
12. Have you been able to be understood partially when speaking with people who do not know you?
- Yes  
 No  
 Don't know  
 Refused
13. During the past week, have you been able to be understood completely when speaking with people who know you well?
- Yes -> Go to 16  
 No  
 Don't know  
 Refused
14. Have you been able to be understood partially when speaking with people who know you well?
- Yes -> Go to 16  
 No  
 Don't know  
 Refused
15. During the past week have you been able to speak at all?
- Yes  
 No  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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## GETTING AROUND

16. During the past week, have you been able to bend, lift, jump and run without difficulty and without help or equipment of any kind?
- Yes -> Go to 24  
 No  
 Don't know  
 Refused
17. Have you been able to walk around the neighborhood without difficulty and without help or equipment of any kind?
- Yes -> Go to 24  
 No  
 Don't know  
 Refused
18. Have you been able to walk around the neighborhood with difficulty but without help or equipment of any kind?
- Yes -> Go to 24  
 No  
 Don't know  
 Refused
19. During the past week, have you been able to walk at all?
- Yes  
 No -> Go to 22  
 Don't know  
 Refused
20. Have you needed mechanical support, such as braces or a cane or crutches, to be able to walk around the neighborhood?
- Yes  
 No  
 Don't know  
 Refused
21. Have you needed the help of another person to walk?
- Yes  
 No  
 Don't know  
 Refused
22. Have you needed a wheelchair to get around the neighborhood?
- Yes  
 No  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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23. Have you needed the help of another person to get around in the wheelchair?

- Yes  
 No  
 Don't know  
 Refused

#### HANDS AND FINGERS

24. During the past week, have you had the full use of both hands and ten fingers?

- Yes -> Go to 28  
 No  
 Don't know  
 Refused

25. Have you needed the help of another person because of limitations in the use of your hands or fingers?

- Yes  
 No -> Go to 27  
 Don't know  
 Refused

26. Have you needed the help of another person with some tasks, most tasks, or all tasks?

- Some tasks  
 Most tasks  
 All tasks  
 Don't know  
 Refused

27. Have you needed special equipment, for example special tools to help with dressing or eating, because of limitations in the use of your hands or fingers?

- Yes  
 No  
 Don't know  
 Refused

#### SELF-CARE

28. During the past week, have you been able to eat, bathe, dress and use the toilet without difficulty?

- Yes -> Go to 31  
 No  
 Don't know  
 Refused

29. Have you needed the help of another person to eat, bathe, dress or use the toilet?

- Yes  
 No  
 Don't know  
 Refused

30. Have you needed special equipment or tools to eat, bathe, dress and use the toilet?

- Yes  
 No  
 Don't know  
 Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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## FEELINGS

31. During the past week, have you been feeling happy or unhappy?
- Happy
  - Unhappy -> Go to 33
  - Don't know
  - Refused
32. Would you describe yourself as having felt:
- a) happy and interested in life, or
  - b) somewhat happy?
- a -> Go to 34
  - b -> Go to 34
  - Don't know
  - Refused
33. Would you describe yourself as having felt:
- a) somewhat unhappy
  - b) very unhappy
  - c) so unhappy that life was not worthwhile
- a
  - b
  - c
  - Don't know
  - Refused
34. During the past week did you ever feel fretful, angry, irritable, anxious or depressed?
- Yes
  - No -> Go to 37
  - Don't know
  - Refused
35. How often did you feel fretful, angry, irritable, anxious or depressed: rarely, occasionally, often, or almost always?
- Rarely
  - Occasionally
  - Often
  - Almost always
  - Don't know
  - Refused
36. During the past week did you feel extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help?
- Yes
  - No
  - Don't know
  - Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

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**MEMORY**

37. How would you describe your ability to remember things, during the past week:
- (a)able to remember most things  a
  - (b)somewhat forgetful  b
  - (c)very forgetful  c
  - (d)unable to remember anything at all?  d
  - Don't know
  - Refused

**THINKING**

38. How would you describe your ability to think and solve day to day problems, during the past week:
- (a)able to think clearly and solve problems  a
  - (b)had a little difficulty  b
  - (c)had some difficulty  c
  - (d)had a great deal of difficulty  d
  - (e)unable to think or solve problems?  e
  - Don't know
  - Refused

**PAIN AND DISCOMFORT**

39. Have you had any trouble with pain or discomfort, during the past week?
- Yes
  - No -> Go to 41
  - Don't know
  - Refused
40. How many of your activities, during the past week, were limited by pain or discomfort: none, a few, some, most, all?
- None
  - A few
  - Some
  - Most
  - Don't know
  - Refused
41. Overall, how would you rate your health during the past week?
- (a)excellent  a
  - (b)very good  b
  - (c)good  c
  - (d)fair  d
  - (e)poor  e
  - Don't know
  - Refused

Hospital No.

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Patient ID

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Patient Initials

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Date Form Completed (mm/dd/yy)

		/			/		
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FOR STUDY COORDINATOR USE ONLY

1. Who answered the questions on this form (check one)?

- Study Subject
- Someone who lives with the subject
- Someone who does not live with the subject
- No-one

2. Were all questions answered? .....  Yes  No

If No, please give reason:

--

3. If the questionnaire was not completed, indicate the main reason (check one)

- Subject deceased and no-one else was available
- Subject could not be contacted
- Subject refused to complete
- Subject could not complete due to illness or other reason and no-one else was available
- Questionnaire not administered due to institution error
- Other, specify

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That's the end of the survey. Thank you.

Staff Initials

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**U. Instructions for Form 20N – Patient Diary for Non-VA Patients**

Please give this diary to the patient before the patient's release from the hospital for the hospitalization in which he/she was enrolled in the study. Instruct him/her to fill it out each time he/she obtains healthcare from a doctor, at a hospital, or at a nursing home outside the hospital where he/she was treated for kidney failure. Inform the patient that you will be calling him/her twice to obtain this information, once at approximately 2 months after he/she was enrolled in the ATN study, and the second time will be approximately one year after enrollment into the study.

Note: The patient keeps this diary to remind him/her of healthcare received since the last time he/she was contacted by a study member. This form does not get sent to the West Haven Coordinating Study.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 20N  
PATIENT DIARY FOR NON-VA PATIENTS  
TO RECORD HEALTHCARE OUTSIDE THE STUDY HOSPITAL

Patient Instructions

Please fill out this form whenever you obtain healthcare outside of the hospital where you were treated for kidney failure, from today until \_\_\_\_\_, 20\_\_\_\_. Someone will contact you twice in the next 12 months to ask about healthcare you obtained outside of that hospital. Please keep the diary handy and refer to it when answering the questions.

Thank you!

- I. Doctor Visits (do not include visits to doctors at the hospital where you were treated for kidney failure)

DATE AND PLACE

- |           |                                              |                              |                             |
|-----------|----------------------------------------------|------------------------------|-----------------------------|
| 1. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 7. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 8. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 9. _____  | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 10. _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 11. _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 12. _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13. _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 14. _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 15. _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

**Instructions for Form 20V – Patient Diary for VA Patients**

Please give this diary to the patient before the patient's release from the hospital for the hospitalization in which he/she was enrolled in the study. Instruct him/her to fill it out each time he/she obtains healthcare from a doctor, at a hospital, or at a nursing home outside the VA system. Inform the patient that you will be calling him/her twice to obtain this information, once at approximately 2 months after he/she was enrolled into the ATN study, and the second time will be approximately one year after enrollment into the study.

Note: The patient keeps this diary to remind him/her of healthcare received since the last time he/she was contacted by a study member. This form does not get sent to the West Haven Coordinating Study.

VA WEST HAVEN CSP530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 20V  
PATIENT DIARY FOR VA PATIENTS  
TO RECORD HEALTHCARE OUTSIDE THE VA SYSTEM

Patient Instructions

Please fill out this form whenever you obtain healthcare outside the VA system, from today until \_\_\_\_\_, 20\_\_\_\_. Someone will contact you twice in the next 12 months to ask about healthcare you obtained outside the VA system. Please keep the diary handy and refer to it when answering the questions.

Thank you!

I. Doctor Visits (do not include visits to VA doctors)

DATE AND PLACE

- |     |       |                                              |                              |                             |
|-----|-------|----------------------------------------------|------------------------------|-----------------------------|
| 1.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 7.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 8.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 9.  | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 10. | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 11. | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 12. | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13. | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 14. | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 15. | _____ | Primary purpose of visit was kidney trouble? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

**V. Instructions for Form 21 – Biorepository Specimen Confirmation**

**Enter the Hospital Number, the Patient ID, the Patient Initials, and Date Form Completed at the top of the form.**

**When to complete this form: If biorepository specimens have been collected from the patient, complete this form at the time the shipment of the specimens is sent to MAVERIC. If biorepository specimens have not been collected from the patient, complete this form on study day 8 or day of study exit, whichever comes first.**

**Note: This form is to be completed for every patient enrolled in the study whether or not biorepository specimens have been collected from the patient. Send the original of this form to WH CSPCC and make a copy of it for the patient's study file.**

- I. Mark 'yes' if consent was given to draw blood samples for the biorepository; mark 'no' otherwise.
  - A. If 'no' is marked, skip to the end of the form, fill in the staff initials at the bottom of the form, and send this form to West Haven CSPCC.
  - A. If 'yes' is marked, complete sections B.1 B.2, and B.3 of this form.
    1. Mark 'yes' if specimen 1 was obtained; mark 'no' otherwise.
      - a. If 'yes',
        - i. Enter the date the specimen was obtained as mm/dd/yy.
        - ii. Affix the specimen label in the space provided.
      - b. If 'no', check the one reason that best describes why the specimen was not obtained. If 'other' is checked, specify the reason in the box provided.
    2. Mark 'yes' if specimen 2 was obtained; mark 'no' otherwise.
      - a. If 'yes',
        - i. Enter the date the specimen was obtained as mm/dd/yy.
        - ii. Affix the specimen label in the space provided.
      - b. If 'no', check the one reason that best describes why the specimen was not obtained. If 'other' is checked, specify the reason in the box provided.

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 21 - BIOREPOSITORY SPECIMEN CONFIRMATION

Hospital No.

[ ][ ][ ]

Patient ID

[ ][ ][ ]

Patient Initials

[ ][ ][ ]

Date Form Completed (mm/dd/yy)

[ ][ ] / [ ][ ] / [ ][ ]

NOTE: THIS FORM IS TO BE COMPLETED FOR EVERY PATIENT ENROLLED IN THE STUDY.

I. Did patient/surrogate consent to have blood samples drawn for the biorepository? ----- Yes  No

A. If No, skip to the end of form.

B. If Yes,

1. Was specimen 1 obtained (i.e. the specimen for study day 1)?-----Yes  No

a. If yes,

i. Date specimen obtained [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

ii. Affix label for specimen

Affix label here

b. If no, give reason specimen not obtained (check one)

- patient refused
- died
- withdrew from study
- missed blood draw
- other, specify

[ ]

2. Was specimen 2 obtained (i.e. the specimen for study day 8)?-----Yes  No

a. If yes,

i. Date specimen obtained [ ][ ] / [ ][ ] / [ ][ ] (mm/dd/yy)

ii. Affix label for specimen

Affix label here

b. If no, give reason specimen not obtained (check one).

- patient refused
- died
- withdrew from study
- missed blood draw
- other, specify

[ ]

**Instructions for Form 21 – Biorepository Specimen Confirmation**

**Enter the Hospital Number, the Patient ID, the Patient Initials, and Date Form Completed at the top of the form.**

3. Mark 'yes' if a shipment was sent to MAVERIC with at least one specimen for this patient; mark 'no' otherwise.
  - a. If 'yes',
    - i. Enter the date the shipment was sent to MAVERIC as mm/dd/yy.
    - ii. Enter the FedEx tracking number for the shipment.
  - b. If 'no', check one box for the reason no shipment was sent to MAVERIC. If 'other' is checked, specify the reason in the box provided.

Enter the initials of the staff member who completed this form.

VA WEST HAVEN CSP 530  
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)  
FORM 21 - BIOREPOSITORY SPECIMEN CONFIRMATION

Hospital No.

--	--	--

Patient ID

--	--	--

Patient Initials

--	--	--

3. Was a shipment sent to MAVERIC with at least one specimen for this patient? ....Yes  No

a. If yes,

i. Date of shipment

		/			/			(mm/dd/yy)
--	--	---	--	--	---	--	--	------------

ii. FedEx tracking#

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

b. If no, specify reason (check one).

no specimens obtained

other, specify

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Note: Send the original of this Form to the West Haven CSPCC for every patient enrolled in the study and make a copy for the patient's study folder.

Staff Initials

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## **XI. BUDGET AND ADMINISTRATION**

### **A. Budget Issues (Department of Veteran Affairs Centers)**

1. **Personnel & All Other Costs:** All centers will be provided with personnel funds for a full time nurse/study coordinator. The study coordinator will be maintained at full-time throughout the study. The centers will be funded up to 1 month prior to the start-up (pending R&D and IRB approvals) and three months for the closeout period of the study for a maximum duration of 42 months (3.5 years). All other costs of \$2,000 annually per center have been budgeted for miscellaneous expenses, such as supplies for the office and computer, medical supplies, copying charges and express mailings when necessary.
2. **Dialysis and Laboratory Costs:** The following figures are based on the maximum number of patients randomized per year of 10 patients. The study has estimated annual funds of \$13,000 for each center to support costs related to the dialysis costs and \$1,500 for each center to support costs related to the laboratory tests (BUN and Urine Creatinine) costs. The budget estimates the BUN at \$6.88 per test with an average of 6 tests per patient.
3. **Equipment:** All computer equipment required for this study has been purchased and will be distributed to each center. This laptop will be required to use the PDF version of the Teleform case report forms for the collection of study data on each study patient. The equipment will be shipped to the Research Service at each participating VA to the attention of the Administrative Officer. The computer equipment will need to be on the VA Research CMR (equipment inventory list). Receipt of the equipment will need to be verified and serial numbers provided to the West Haven CSPCC. The equipment is as follows:

- (1) DELL Latitude D400 (Pentium M Processor 1.40GHz). Software and a carrying case will be included. (Valued at \$1,800)
  - (2) HP Deskjet 5500 Printer (Valued at \$95)
4. **Funding FY 2003:** The study coordinator position will be budgeted with a start date of August 10, 2003 or based on the actual start date of this position. Personnel and all other costs will be sent to each center. Each center must submit a budget for this fiscal year. Based on this request, West Haven-CSPCC will instruct CSP, VA Central Office to transmit funding to each center. No funds will be transmitted until all R&D and IRB committee approvals are sent to West Haven-CSPCC.
5. **Fiscal Year 2004 (October 2003 – September 2004):** An estimate based on the protocol or actual budget request from the R&D office was submitted to CSP, VA Central Office. This will be your Initial Target Allowance (ITA) for next fiscal year. Any adjustments needed will be made during the fiscal year 2004.
6. **Future Year Budgets (FY 2005 and 2007)** – Budget requests are made a year ahead. A form “Request for Budgetary Support” will be sent with an accompanying letter to all VA participating centers ACOS/R&D offices for Fiscal Year (sample of budget request form on page XI-6). Actual personnel costs should be listed on this form. If there are circumstances, and additional funding is required, a justification will need to be included on the form. This form is signed by the site Investigator and the ACOS for R&D, it is then mailed back to the West Haven – CSPCC. The figures will be reviewed and consolidated, questions will be referred back to the Research Office. This request will be coordinated with your Research Office. Personnel funding for each participating medical center will end three months after the patient follow-up period ends. Last day of funding

projected to be February 14, 2007 based on a patient intake start date of September 15, 2003.

7. **Funding Sources:** The Cooperative Studies Program will provide personnel and all other funds to each participating center in support of this study. The funds will be sent as Program 870/Medical Care (if the coordinator is a nurse) or Program 825/Medical Research (personnel other than nurses and all other costs.)
8. **Change of Site Investigator (SI):** Adequate notice (at least 30 days) to WH-CSPCC must be given if there is going to be a change of SI. This will ensure continuity of funds. A letter from the SI should be sent to Dr. Palevsky informing him of this change with a termination date and recommendation of a new SI. The letter must contain the name of the new SI, start date, CV of the new SI and a copy of their Human Subjects Training, HIPAA and Good Clinical Practice Certificates (copies should be sent to the project manager at WH-CSPCC, along with the “Change of Site Personnel” Form – see page XI-12). Dr. Palevsky will submit a letter with his concurrence to the WH-CSPCC with a copy of all paperwork. This change of investigator will also have to be submitted and approved by your local R&D & IRB Committees. The WH-CSPCC and the Albuquerque Pharmacy must have copies of the R&D & IRB minutes from the medical center approving this change. The WH-CSPCC will issue a letter to the R&D office requesting the minutes upon notification of a SI change. WH-CSPCC will submit the name to the CSP, VACO.

**If an Investigator’s VA status changes during the study to less than 5/8, WH-CSPCC must be notified.** In order to receive funding an Investigator should be 5/8 VA or receive approval through the VA Central Office’s Eligibility Panel. Your Research

Office is familiar with this procedure and can submit the required paperwork for you.

WH-CSPCC must have a copy of the VACO's approval.

9. **VA Centrally Directed Travel (VA Centers):** Upon receiving a request from the Study Chairman or biostatistician to hold a study meeting, the West Haven CSPCC will prepare an estimate of the travel costs to the study meeting. This information will be forwarded to VACO. A FAX authorizing your travel from VACO will be advanced to your station so that you may initiate your travel arrangements and orders. The FAX sent will designate the funding source and the amount of travel funds allocated for your travel (sample fax on XI-5). Currently the program is providing travel funds estimated at \$800 per person in the Initial Target Allowance (ITA) allocated to your center at the beginning of the fiscal year. These funds will be adjusted based on the actual costs of travel. You must always notify your R&D office when you will be traveling and coordinate your travel with that office.

<b>NAME OF AGENCY</b>  VACO WASHINGTON, DC	<b>PRECEDENCE</b>  ACTION:  INFO:	<b>SECURITY CLASSIFICATION</b>																								
<b>ACCOUNTING CLASSIFICATION</b>	<b>DATE PREPARED</b> [DATE]	<b>FILE</b>																								
<b>FOR INFORMATION CALL</b>																										
<b>NAME</b> [TRAVEL CLERK NAME], TRAVEL COORD.	<b>PHONE NUMBER</b> [PHONE NUMBER]	<b>TYPE OF MESSAGE</b> SINGLE      BOOK      MULTIPLE ADDRESS																								
<i>THIS SPACE FOR USE OF COMMUNICATION UNIT</i>																										
<b>MESSAGE TO BE TRANSMITTED (Use double spacing and all capital letters)</b>																										
<p><b>TO:</b></p> <p><u>PLEASE TRANSMIT TO THE LISTED VAMCs:</u></p> <p>00/151 BY DIRECTION OF DEPUTY UNDER SECRETARY FOR HEALTH, PROVIDED YOU CONCUR, CHIEF R&amp;D OFFICER APPROVES TRAVEL FOR <u>THE FOLLOWING INDIVIDUALS</u> TO ATTEND THE CSP #000 [MEETING NAME] ON [DATES], IN [CITY] [STATE]. FUNDING TO SUPPORT THIS DETAIL THROUGH PROGRAM 825 (CODES LISTED BELOW). (LODGING/ MEALS STATEMENT IF APPROPRIATE, {MAY BE PROVIDED}). (PUT IN STATEMENT IF RENTAL CAR REQUIRED.) IF FUNDING CODE INDICATES "COTBS", TDA TO FOLLOW; IF "PYOS" OR "CYOS", USE FUNDS ALREADY ON STATION. ADJUSTMENT WILL BE MADE SUBSEQUENT TO THE TRIP UPON NOTIFICATION OF EXCESS FUNDING OR EXCESS COSTS TO [TRAVEL COORDINATOR'S NAME], CSPCC, [NAME] [STA#/151] OR FAX TO [FAX#].</p> <p>FUNDING CODES:      PYOS-PRIOR YEAR FUNDS ON STATION      APPRO. 36_.0161.007 (.016)                                       CYOS-CURRENT YEAR FUNDS ON STATION      APPRO. 36_.0161.007 (.016)                                       COTBS-CO DIRECTED FUNDS TO BE SENT                                       CY (COTBS)      APPRO. 36_.0161.007 (.016)                                       PY (COTBS)      APPRO. 36_.0161.007 (.016)                                       REIM - REIMBURSABLE FUNDS      <u>APPRO. 36_.0161.001</u>                                       GPF - General Post Funds to be sent from FRI, Inc. to site's GPF account</p> <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width:15%;">Station</th> <th style="width:20%;">Participants</th> <th style="width:15%;">Amount</th> <th style="width:10%;">PYOS</th> <th style="width:10%;">CYOS</th> <th style="width:10%;">COTBS</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>			Station	Participants	Amount	PYOS	CYOS	COTBS																		
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<table border="1" style="margin-left:auto; margin-right:auto;"> <tr> <td style="width:50px;"><b>PAGE NO.</b></td> <td style="width:50px;"><b>NO. OF PGS.</b></td> </tr> <tr> <td style="text-align:center;">1</td> <td style="text-align:center;">1</td> </tr> </table>		<b>PAGE NO.</b>	<b>NO. OF PGS.</b>	1	1	<b>SECURITY CLASSIFICATION</b>																				
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**COOPERATIVE STUDIES PROGRAM, REQUEST FOR BUDGETARY SUPPORT, FY \_\_\_\_**

VA STATION NAME	STATION NO.
COOPERATIVE STUDY NAME	STUDY NO.
INVESTIGATOR'S NAME	SOCIAL SECURITY NO.

INVESTIGATOR'S STUDY TITLE

**1. STATUS (Check One)**

Full-Time	Part-Time VA	Consultant	Attending	WOC
1. <input type="checkbox"/> VA	2. <input type="checkbox"/> (___/8 time)	3. <input type="checkbox"/> (___/6 time)	4. <input type="checkbox"/> (___/8 time)	5. <input type="checkbox"/> (___/8 time)

**2. PERSONNEL - PROJECTED FOR FY 20\_\_**

NAME OF EMPLOYEE (Indicate if new position or vacant)	Grade/Step*	#Paid Pay Periods	Annual Salary <sup>1</sup>	Total Benefits (%)	Actual Salary and Benefits	% of Time	Position Title
				(    %)			
				(    %)			
				(    %)			
				(    %)			
				(    %)			
				(    %)			
				(    %)			
				(    %)			
				(    %)			

\*Use two lines if projected step increase is involved: Indicate number of pay periods and costs at each level.

**3. BUDGET**

ITEM	ACTUAL FY __	ALLOCATION FY __	REQUESTED FOR FY __
Personnel costs including benefits - Program 870 ....	\$ _____	\$ _____	\$ _____
Personnel costs including benefits - Program 825 ....	\$ _____	\$ _____	\$ _____
All other costs (including supplies and equipment) .... (Specify equipment in Remarks)	\$ _____	\$ _____	\$ _____
<b>Total</b>	\$ _____	\$ _____	\$ _____

REMARKS (Use overleaf if necessary)  
<sup>1</sup>Include locality pay.

SIGNATURE OF INVESTIGATOR		SIGNATURE OF ACOS FOR RESEARCH	
FTS NO.	DATE	FTS NO.	DATE

**B. Budgetary Issues (University Centers)**

1. **Personnel and All Other Costs:** These centers will be funded using a performance based plan. It is requested that each center be staffed with two full-time study coordinators/nurses. This position will be funded for the full study duration plus three months for the close-out period. The budget allows for funding 2 investigators @ 10% each for the full study duration plus two months for the close-out period. The all other costs of \$2,000 annually will be used for miscellaneous expenses, such as office and medical supplies, copying charges and express mailings. It is anticipated that each center will enroll 84 eligible patients over the 3 years recruitment period of the study. Each center is encouraged to maximize the rate of recruitment. There is no upper limit to the number of patients a center may enroll. All patients should be followed until the end of the study period. If the site investigator decides to relocate during the course of the study, you should make appropriate arrangements for the successful continuation of the study at your center.
  
2. **Payout Schedule:** The centers will receive start-up costs and 100% of the budget for the first six months of the patient intake period. Each center will receive 50% of their budget for the remaining six months of Year 1 and for all of Years 2 and 3. Additional funding will be based on performance of the study at each center, based on capitated payments of \$3,000 per patient starting with the 15<sup>th</sup> randomized patient. Funding to be distributed as follows:

Start Up (1 month)	=	100% of Budget of 1 month
Year 1 (1-6 months)	=	100% of Budget of 1-6 months
Year 1 (7-12 months)	=	50% of Budget of 7-12 months

\$3,000 per patient after 14<sup>th</sup> patient randomized in Year 1\*

Year 2 (13-24 months)=	50% of Budget \$3,000 per patient randomized in Year 2*
Year 3 (25-36 months)=	50% of Budget \$3,000 per patient randomized in Year 3*
Year 4 (follow up & close out)=	25% of Budget (10-21 pts.) 50% of Budget (22-42 pts.) 75% of Budget (43-63 pts.) 100% of Budget (>64 pts.)

\*Budget estimate based on randomization of 28 patients per year (28 x \$3,000 = \$84,000)

Additional laboratory studies required for the protocol (urine urea nitrogen and creatinine) will be reimbursed at a rate of \$150 per patient randomized.

The cost of additional care for patients treated in the intensive therapy arm will be reimbursed as follows:

Continuous renal replacement therapy (CRRT):

up to \$180 per day for each patient-treatment day at 35ml/kg/hr

Hemodialysis: up to \$420 per treatment for each extra hemodialysis treatment (maximum of 3/week).

Payments will be made on a quarterly basis. The laboratory and dialysis payments will be linked to the Form 9 and Day 28 form. Capitation payments will be generated after the Day 60 form is received. All forms must be submitted to the WH-CSPCC prior to payment.

3. **Equipment:** All computer equipment required for this study has been purchased and will be distributed to each center. This laptop will be required to use the PDF version of the Teleform case report forms for the collection of study data on each study patient. The equipment will be shipped to the Investigator or designated person at each University

center. Receipt of the equipment will need to be verified and serial numbers provided to the West Haven CSPCC. The equipment is as follows:

- (1) DELL Latitude D400 (Pentium M Processor 1.40GHz). Software and a carrying case will be included. (Valued at \$1,800)
- (2) HP Deskjet 5500 (Valued at \$95)

4. **Change of Site Investigator (SI):** Adequate notice (at least 30 days) to WH-CSPCC must be given if there is going to be a change of SI. This will ensure continuity of funds. A letter from the SI should be sent to Dr. Palevsky informing him of this change. The letter must contain the name of the new SI, start date, CV of the new SI along with a copy of their Human Subjects Training, HIPAA and Good Clinical Practice Certificates. Dr. Palevsky will submit a letter with his concurrence to Dr. Starr for NIDDK approval and then forward to the WH-CSPCC with a copy of all paperwork. This change of investigator will also have to be submitted and approved by your local IRB Committee. The WH-CSPCC and the Albuquerque Pharmacy must have copies of the IRB minutes from the medical center approving this change. The WH-CSPCC will issue a letter to the University requesting the minutes upon notification of a SI change. WH-CSPCC will submit the name to the CSP, VACO.
5. **Travel:** Upon receiving a request from the Study Chairman or biostatistician to hold a study meeting, the West Haven CSPCC will prepare an estimate of the travel costs to the study meeting. This information will be forwarded to VACO for approval. Confirmation regarding the meeting location, dates and time will be sent to sites for you to initiate your travel arrangements at your institution. The University will invoice WH-CSPCC for reimbursement.

**C. General Procedures (VA and University Centers)**

1. **Requesting Additional Funding:** Any requests for additional funding must be approved by the Study Chairman and the West Haven-CSPCC (NIDDK will also review all University Center requests). Please submit your requests with the details to Dr. Peter Peduzzi through Dr. Paul Palevsky, Study Chairman (addresses below). Dr. Palevsky will review the request and forward it to Elizabeth Jobes, Project Manager for review. The Project Manager will submit the request to Dr. Peduzzi. The request will be reviewed and a written response will be made. These requests must be coordinated and sent from your Research Office. Requests can be faxed or e-mailed to the appropriate offices.

Peter Peduzzi, Ph.D.  
Director  
CSPCC/151A  
VA Connecticut Healthcare  
950 Campbell Avenue  
West Haven, CT 06516  
Fax: 203-937-3858  
Email: [peter.peduzzi@yale.edu](mailto:peter.peduzzi@yale.edu)

Thomas Roy  
Project Manager  
CSPCC/151A  
VA Connecticut Healthcare  
950 Campbell Avenue  
West Haven, CT 06516  
Fax: 203-937-3858  
Email: [Thomas.roy@yale.edu](mailto:Thomas.roy@yale.edu)

Paul Palevsky, M.D.  
Study Chairman (CSP#530)  
VA Pittsburgh Healthcare System  
University Drive Division  
Room 7E123 (111F-U)  
Pittsburgh, PA 15240-0001  
Fax: 412-688-6908  
Email: [palevsky@pitt.edu](mailto:palevsky@pitt.edu)

Robert Star, MD  
Senior Scientific Advisor, NIDDK  
Building 1, Room 218  
1 Center Drive  
Bethesda, MD 20892-0166  
Fax: 301-402-0280  
Email: [starr@extra.niddk.nih.gov](mailto:starr@extra.niddk.nih.gov)

2. **West Haven Center Correspondence Form:** The Center Correspondence Form is located on the next page. Whenever there are changes in mailing address, telephone numbers, or change in participating investigator or nurse/study coordinator, complete the form with changes and FAX to WH-CSPCC (203-937-3858) as soon as possible.

You can contact the Project Manager for any assistance or information you may require regarding budget at the West Haven Cooperative Studies Program Coordinating Center Thomas Roy, Project Manager, West Haven-CSPCC, Phone: 203-932-5711 ext. 3761, Fax: 203-937-3858, Email: [Thomas.roy@yale.edu](mailto:Thomas.roy@yale.edu)

**WEST HAVEN COOPERATIVE STUDIES PROGRAM**  
**CSP #530- ATN**  
**CHANGE OF SITE PERSONNEL**

*This information is needed for administrative purposes (funding, publications)*

**VAMC:** \_\_\_\_\_ **Site #** \_\_\_\_\_

**Date:** \_\_\_/\_\_\_/\_\_\_

**Please check the appropriate box and print clearly.**

Participating Investigator

**Investigators must have  
Approval from Chairman's  
Office. Also, 1572 with CV to  
Albuquerque Pharmacy**

**Current:** \_\_\_\_\_ **Start Date:** \_\_\_/\_\_\_/\_\_\_

**Name:** \_\_\_\_\_ **SS#:** \_\_\_\_-\_\_\_\_-\_\_\_\_  
Last First Title

**Address:** \_\_\_\_\_ **E-mail:** \_\_\_\_\_

**Section Title:** \_\_\_\_\_

**Phone:** ( ) \_\_\_\_\_ **FAX:** \_\_\_\_\_

**Previous:**

**Name:** \_\_\_\_\_ **Ending Date** \_\_\_/\_\_\_/\_\_\_  
Last First Title

Study Coordinator

**Current:** \_\_\_\_\_ **Start Date:** \_\_\_/\_\_\_/\_\_\_

**Name:** \_\_\_\_\_  
Last First Title

**Address:** \_\_\_\_\_ **E-mail:** \_\_\_\_\_

**Phone:** ( ) \_\_\_\_\_ **FAX:** \_\_\_\_\_

**Previous:**

**Name:** \_\_\_\_\_ **Ending Date** \_\_\_/\_\_\_/\_\_\_  
Last First Title

FAX Form to (203) 937-3858 or Send Original to:

*(Include copy of Human Subjects Training Certificate,  
as well as HIPAA and GCP Training Certificates)*

Thomas Roy, Project Manager  
VAMC-CSPCC (151A) Bldg 35  
950 Campbell Avenue  
West Haven, CT 06516

## **XII. DATA QUALITY ASSURANCE**

This trial will compare a strategy of intensive renal support to conventional management of renal replacement therapy in critically ill patients. To be able to accurately measure the effect of the study treatments, it is imperative that complete, accurate and reliable data is collected and recorded. The West Haven Coordinating Center staff will check all submitted data forms for timeliness, correctness, and completeness. For data quality assurance, periodic requests will be made to individual study centers for clarification of incomplete or inappropriately entered information. To accomplish these goals this section contains sample reports that elicit information from your site or check and report on information collected from your site.

### **A. Records of Forms Sent**

Complete this record and send a copy of it with each package of completed data forms you send to West Haven CSPCC. Keep the original of it for your study files. This form is a record for you and for the coordinating center to show which forms are contained in each package of data forms sent to West Haven from your site and to show the date on which the package was sent. Enter the patient ID in the first column, the date that appears at the top the particular form in the second column, and check the box under the column that specifies which form this is for that patient.



## **B. Data-Check Error Report and Requests for Data Edits**

As part of an ongoing quality assurance program, the CSP Coordinating Center will periodically generate computerized data checks on all data forms submitted from each site. When these data checks detect errors in the data forms, for example, a missing value or a measured value outside the range of expected values, a request for corrections will be mailed to the individual study site using a Data Edit Report. A sample of the Data Edit Report, an explanation of its contents, and the instructions for its completion are given in this section

Study personnel at the site will be asked to correct the error in the coding or to supply the missing data. Corrections will be made in the Data Edit Report that must be initialed by the Editor, dated and promptly returned to the Coordinating Center. The reports should be returned within two weeks from the date of receipt. In adherence to Good Clinical Practice Guidelines, no changes in the original data are permissible without proper documentation. Data corrections/changes should be noted in blank areas on the CRF near the original entry without obscuring it. The original data should be crossed out with a single line. The date of the change, as well as the initials of the person making the change, must be noted. All changes in the original data will be recorded on the copy of the data form at the participating center as well as at CSPCC (i.e. change, date of change and person responsible for change).

**1. Data Edit Report Detailed Instructions** -These are specific instructions regarding completion of a Data Edit report.

**a. Purpose:** The Data Edit report is used as a request for data correction and/or changes to the original data. These are computerized data checks based on information from individual study sites.

**b. Procedure:** Study personnel such as the Nurse Coordinator or Principal Investigator must complete the Data Edit report. Please refer to your Operations Manual for General Coding and Data Form instructions.

**c. Hospital number** - At the top of the sheet on the left side will be the hospital name and site number.

**d. Out-of-Range or Missing Information**, the title of the sheet, will be centered at the top of the columns to indicate the type of information being checked.

**2. Description of the Data Edit Form/Data Edit Form Columns**

**a. Patient ID** - This is the subject identification number, which is a specific 6-digit number that is assigned to each subject. It is composed of the 3 digits of the site number followed by the 3 digits of the patient ID and is supplied on the report by CSPCC.

**b. Form** - This is the number of the form that contains the error. This information is supplied by CSPCC.

**c. Date of Form** – This date column is either for date of completion or date in the header section at the top of the data form containing the edit. This information is supplied by CSPCC.

**d. Number** – This is the copy number of the form for the specified date. This will only be used when more than one copy of a form may be submitted on the same day, e.g. Form 16, SAE Form.

**e. Item Description** – This column is a description of the field or variable generating the query. This information is supplied by CSPCC.

**f. Error** – This column describes the error that was detected by the computerized data check. This information is supplied by CSPCC.

**g. Error messages** - As part of the data check process, the data check program generates short data error messages. These messages appear under the Error column on the data edit sheets sent to sites. The table below provides a detailed explanation of each message.

### Standard Messages

Short Message	Detail Description
Less than min	The data value is less than a predefined minimum value. The data value may be a number or letters.
Greater than max	The data value is greater than a predefined maximum value. The data value may be a number or letters.
Field is Blank or Missing	The box on the form was not filled in, so there is no data value for this item.
Value out of range	The data value was compared to a list of valid data values and was not in the list.

**h. Current Value** – This column is the current value that caused the corresponding data edit. This information is supplied by CSPCC. If the data in the Current Value Column is correct then leave the New Value Column blank, initial, date, and sign the form.

However, if the value is incorrect please write the correct data in New Value Column.

**i. New Value**- This column is for the study site to enter the correct value for the corresponding data edit. Please write as neatly as possible and make entries within the boxes provided on the data edit sheet.

**j. Initials of Editor** – All data edits must be initialed.

**k. Date of Edit** – The date the edit/change was made.

**l. Signature and Date** – This sheet must be signed and dated by the Coordinator or P.I. only. A signature indicates the information on the Data-Edit report is confirmed and accurate.

If you have any questions or problems concerning form completion or submission, please contact the CSP 530 research coordinator at the Coordinating Center [**Vanessa McBride at 203/932-5711x3790**].

See sample edit report below

*WEST HAVEN Cooperative Studies Coordinating Center  
Study # 530 - ATN Study*

Hospital=Site Name (Number) Patient ID=#

Out-of-Range or Missing Information								
Form	Date of Form	Number	Item Description	Error	Current Value	New Value	Initials of Editor	Date of Edit

Please make a copy of this form and file it in the patient's study records and return the completed and signed original by the *date shown* to:

**Vanessa McBride  
Research Associate CSPCC  
VA Medical Center 151A  
950 Campbell Avenue  
West Haven, CT 06516**

\_\_\_\_\_  
Signature of Coordinator or P.I                      Date

### **C. The Signature Log**

All personnel involved with the study must sign the signature log. An example of the signature log for you to copy and complete is shown on the next page. A copy of this log should be sent to West Haven CSPCC every time there is a change in personnel at your site. The PI at a site is responsible for seeing that this log is always filled out and sent to West Haven CSPCC in a timely manner, as well as being responsible for the conduct of the study at his/her site and for the supervision of all study site personnel.

**A. Site Signature Log – ATN Study CSP# 530**

**INVESTIGATOR'S NAME:** \_\_\_\_\_

**STUDY SITE & NUMBER** \_\_\_\_\_

DATE	NAME (Print/Type)	TITLE	SIGNATURE	INITIALS (Print)

Please make a copy of this form, file it in your Central Study File and send the original to:

Vanessa McBride  
Research Associate CSPCC  
VA Medical Center 151A  
950 Campbell Avenue  
West Haven, CT 06516

#### **D. Screened/Randomized Patient Log**

Each site should keep a log of screened and randomized patients. On the next page is a sample of such a log, but you may design one that is more suitable for your site.



## **E. Schedule of Follow-up Form**

This form will automatically be generated by the ITTRS phone randomization system each time you randomize a patient. It contains the patient id, patient initials, and date of randomization for the patient. It also indicates the approximate dates for the 28-day, the 60-day, and the one-year follow-up for the patient. This schedule will automatically be faxed to you by the ITTRS each time you call it and successfully randomize a patient into the study.

A sample of the schedule of follow-up appears on the next page. For each patient randomized at your site, the schedule of follow-up form reminds you to (1) complete Form 11 on study day 28 or upon exit of the patient from the study, whichever comes first; (2) complete Form 12 on study day 60 or upon exit of the patient from the study, whichever comes first; (3) complete the two telephone surveys, Form 17 (N or V) and Form 19 (S or P), as near as possible to study day 60; and (4) complete the two telephone surveys, Form 18 (N or V) and Form 19 (S or P), as near as possible to one year after the patient was randomized into the study

**Sample Schedule of Follow-up Form**

VA COOPERATIVE STUDY NO. 530  
INTENSIVE vs CONVENTIONAL RENAL SUPPORT IN ACUTE RENAL FAILURE  
(101) Dummy2

Patient ID: 006

Date of Randomization: May 21<sup>st</sup>, 2003

Patient's Initials: LWX

<b>Study Day</b>	<b>Date Due</b>	<b>Forms Required</b>
Day 28	Jun 18 <sup>th</sup> , 2003	11 _____
Day 60	Jul 20 <sup>th</sup> , 2003	12 _____ 17 N/V* _____ 19 S/P** _____
1 year	May 21 <sup>st</sup> , 2004	18N/V* _____ 19 S/P** _____

\*N for non-VA sites, V for VA sites

\*\*S if subject is being interviewed, P if proxy is being interviewed

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### **XIII. BIOREPOSITORY SPECIMEN COLLECTION AND SHIPPING**

#### **Procedures for Collecting and Shipping ATN Blood Samples**

Participants will have 19 ml blood drawn (1 x 9 ml EDTA tube and 1 x 10 ml serum tube) on day one and on day 8. If patients are being treated with intermittent hemodialysis, the samples will be drawn at the initiation of therapy on each day. The blood tubes will be centrifuged on site, aliquoted into pre-labeled cryovials, and stored frozen until shipped to the MAVERIC Core Laboratory. Blood collection, processing and shipping supplies will be provided by MAVERIC. The kits will include the following supplies:

#### ***ATN Blood Collection Supplies:***

- 1 x 10 ml serum tube (red top)
- 1 x 9 ml EDTA blood tube (lavender top)

#### ***ATN Blood Processing Supplies:***

- cryovials
- pre-printed cryolabels with study identifier
- disposable transfer pipettes

#### ***ATN Shipping Supplies:***

- insulated shipping containers
- plastic secondary container with absorbant
- all required shipping labels
- pre-addressed and pre-paid FedEx air bills

#### ***Instructions for Blood Draw:***

Write the participant's study number on one lavender top and one red top tube. Place the plasma tube (lavender top) on ice. Samples will be drawn through the dialysis catheter. Immediately after filling the tubes:

- a. **Invert the plasma tube 8-10 times** to mix the blood and place on ice until centrifuged.
- b. **Invert the serum tube 5 times** and stand the red top tube upright in a rack for 30-60 minutes at room temp to allow the blood to clot.

#### ***Labeling Procedure:***

- a. **Labels.** Preprinted labels will be sent to each participating site along with the blood drawing and shipping supplies. These barcode labels are specially designed for freezers and will remain on the cryovials even at  $-190^{\circ}\text{C}$  if used properly. **The labels must be placed on the cryovials at room temperature**—they will not adhere

properly to a cold vial. Each sheet of labels will include 5 sets of labels. Each set of labels will contain cryolabels for 3 plasma vials and 3 serum vials for specimens obtained from two draws per patient (day 1 and day 8). Three additional labels are provided for paperwork. Use the provided Supply Request Form to order additional labels as needed.

b. **Coding.** The labels [RF XXXYYY-D PE or SER or WH or MAV] for each patient are coded as follows:

- RF = a MAVERIC study identifier
- XXX = your 3-digit site identifier
- YYY = the patient identifier
- D = 1 or 8 day of draw (day 1 or day 8)
- PE = EDTA plasma (lavender top tube)
- SER = Serum (red top tube)
- WH = West Haven
- MAV = MAVERIC

c. **Label placement.** Label 6 Nunc cryotubes (3 PE and 3 SER) with the appropriate bar-coded labels. **Make certain to use the label with the correct patient identifier.** (It is good practice to deface or throw away labels with patient identifiers from patients that did not qualify for the study.) Place the bar-coded labels on the cryovials so that the numbers are read along the length of the tube. Do not wrap the labels around the tube or the scanner will not be able to read the barcode. It is convenient to use the vertical line on the cryotube as a guide. Place the top of the label close to the top of the vial but not over the cap!

**NOTE:** The **WH** labels should be attached to the West Haven CSPCC Form 21 (Biorepository Specimen Confirmation Form). The **MAV** label should be attached to the Shipment Packing List/Notification FAXSIMILE Form.

***Processing the samples:***

- a. **Samples should be centrifuged within 1 hour of collection.** If the samples are not centrifuged immediately, place on ice until processed.
- b. Centrifuge the blood tubes for 15 min at 1300 x g at 4° C.
- c. Do not leave specimens in centrifuge for more than 30 minutes.
- d. Use a disposable pipet to aliquot approximately 1.5 ml of plasma (lavender top tube) into the PE -labeled cryovials. Do not disturb the red blood cells.
- e. Use a second pipet to aliquot the serum (red top tube) into the SER-labeled cryovials.
- f. Screw caps onto the cryovials and freeze the vials (preferably at < -40° C, but vials can be frozen at -20° C for two weeks) until shipped to the MAVERIC Laboratory. The cryovials containing the aliquoted specimens may be stored in the plastic secondary shipping container.

***Shipments to MAVERIC Core Laboratory:***

Call FedEx (1-800-Go-FedEx) to assure next-day/same-day pick-ups in your local area and to schedule the approximate time and exact location of the pick-up. **Dry ice packages should not be left at FedEx drop off sites as FedEx can (and sometimes will) refuse to take these boxes. Be sure to specify that this is a blood specimen and it must arrive in Boston the next day.**

- The Specimen Freezer box is placed inside the larger Styrofoam shipping cooler.
- Fill the Styrofoam shipping box with dry ice. This amount of dry ice allows for a one-day delay in the FedEx delivery of the shipment and assures that the specimen(s) will still be frozen upon arrival at MAVERIC.
- Place the Styrofoam cover on the top
- Complete the Shipment Log and copy. Place form on top of the insulated box. Shipping regulations require a list of contents in the box. Close and seal the cardboard box.

***Labeling of Shipping Box:***

The shipping box sent to you should have all appropriate labels, but the shipper is responsible for the shipment so you should confirm the box contains the following labels:

- Shipper's and consignee's addresses.
- A Diagnostic Specimen Label:

**DIAGNOSTIC SPECIMENS**

Packed in compliance with IATA Packing Instruction 650

- A dry ice label with the amount (kg) of dry ice filled in.

Complete and attach the FedEx Air bill. Check the box on the air bill indicating the package contains hazardous material, but a shipper's declaration is not required. Fill in the dry ice information making sure it agrees with the label on the box.

Leave the package exactly where you told the courier to pick it up at the designated pick up time.

***Notify MAVERIC of the Shipment:***

**FAX the completed Shipment Log to the MAVERIC Core Laboratory.** Please include the 12-digit FedEx tracking number. Fax to: MAVERIC Core Laboratory at (857) 364-6678.

**If you have any questions, please call the MAVERIC at:  
(617) 232 - 9500 extension 5664**

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# MAVERIC Core Laboratory

## Shipment Packing List and Notification FAXSIMILE

### ATN STUDY (CSP #530)

Fax: 857-364-6678

Date of Fax/Shipment: \_\_\_\_\_

Study Coordinator: \_\_\_\_\_

Phone: \_\_\_\_\_ Site: \_\_\_\_\_

Write in the FedEx Tracking Number in the box below. For each sample, place the pre-printed specimen label containing MAV on the sheet and enter the date of the blood draws. The inner shipping container holds a maximum of 25 vials, enough for specimens obtained from two patients. FAX this form to MAVERIC and enclose with the shipment.

<b>FedEx Tracking # (12 digits)</b> _____		
<p style="text-align: center;"><b>Sample # 1</b></p> <p style="text-align: center;">Place Pt Specimen Label Here</p>	<p style="text-align: center;"><b>Date of 1<sup>st</sup> Draw:</b></p> <p style="text-align: center;">_____</p> <p style="text-align: center;">3 Vials Plasma 3 Vials Serum</p>	<p style="text-align: center;"><b>Date of 2<sup>nd</sup> Draw:</b></p> <p style="text-align: center;">_____</p> <p style="text-align: center;">3 Vials Plasma 3 Vials Serum</p>
<p style="text-align: center;"><b>Sample # 2</b></p> <p style="text-align: center;">Place Pt Specimen Label Here</p>	<p style="text-align: center;"><b>Date of 1<sup>st</sup> Draw:</b></p> <p style="text-align: center;">_____</p> <p style="text-align: center;">3 Vials Plasma 3 Vials Serum</p>	<p style="text-align: center;"><b>Date of 2<sup>nd</sup> Draw:</b></p> <p style="text-align: center;">_____</p> <p style="text-align: center;">3 Vials Plasma 3 Vials Serum</p>

**Dry ice shipments are best sent on Monday - Wednesday.  
DO NOT ship samples on Fridays or the day before a holiday.**

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**MAVERIC**  
MASSACHUSETTS VETERANS EPIDEMIOLOGY  
RESEARCH AND INFORMATION CENTER

**ATN STUDY (CSP #530)**  
**SUPPLY REQUEST**

**MAVERIC CORE LAB**

Fax # 857-364-6678

Phone # 617-232-9500 x 5664

DATE REQUESTED: \_\_\_\_\_

FROM: \_\_\_\_\_

SITE: \_\_\_\_\_ TELEPHONE # \_\_\_\_\_

DATE NEEDED: \_\_\_\_\_

**QUANTITY ITEM**

\_\_\_\_\_ Blood draw kit with shipping box  
\_\_\_\_\_ Blood draw kit without shipping box  
\_\_\_\_\_ Preprinted Fed Ex Air bill  
\_\_\_\_\_ 9 ml EDTA tube  
\_\_\_\_\_ 10 ml Serum tube  
\_\_\_\_\_ Cryovials  
\_\_\_\_\_ Disposable transfer pipettes  
\_\_\_\_\_ Other \_\_\_\_\_

\_\_\_\_\_ **Bar-coded labels** (Please indicate the patient specimen numbers in the NOTES section below.)

NOTES: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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## **XIV. PHARMACY/DRUG HANDLING**

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Cooperative Studies Program  
Clinical Research Pharmacy  
Coordinating Center  
(CSPCRPCC)  
Information

DRUG HANDLING PROCEDURES

DRUG INFORMATION

SERIOUS ADVERSE EVENT INFORMATION

CSP #530

Intensive vs Conventional Renal Support  
in Acute Renal Failure

September 9, 2003

Prepared by:  
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Regulatory Affairs/Adverse Event Specialist  
CSPCRPCC (151-I)  
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Albuquerque, NM 87106  
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Fax (505) 248-3205

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**A. Introduction and Purpose**

**B. Drug Treatment and Handling Procedures**

**C. Drug Information**

**D. Drug Accountability**

**E. Reporting Serious Adverse Events**

## **A. Introduction and Purpose**

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### **Rational:**

The rationale for CSP #530, Intensive versus Conventional Renal Support in Acute Renal Failure, is to provide evidence that more intensive renal support in critically ill patients may result in improved survival. The study is designed to reflect actual practice patterns used and deliver a dose of dialysis that is at least equivalent to the recommended practice guidelines.

### **Introduction:**

CSP #530, Intensive versus Conventional Renal Support in Acute Renal Failure, is a multi-center, prospective, randomized, parallel-group trial of two treatment strategies for the management of renal support in acute renal failure in critically ill patients. Patients to be included in the trial must have acute renal failure (ARF) consistent with a diagnosis of acute tubular necrosis, the need for renal replacement therapy as determined by the treatment team, an increase in serum creatinine of greater than or equal to 2.0mg/dL (1.5mg/dL in females) over a period not to exceed 4 days, and one non-renal organ failure or sepsis.

The primary objective of the study protocol is to determine if intensive renal support decreases mortality in critically ill patients with ARF as compared to conventional management of renal replacement therapy. Intensive renal support will be defined as either intermittent hemodialysis of 6-times per week with a target delivered spKt/V of approximately 1.2/treatment for hemodynamically stable patients or continuous venovenous hemodiafiltration (CVVHDF) at 35ml/kg/hour. Alternatively, intensive renal support in hemodynamically unstable patients may utilize sustained low efficiency dialysis (SLED) provided 6-times per week. Conventional renal management is defined as intermittent hemodialysis of 3 times per week with a target delivered spKt/V of approximately 1.2/treatment for hemodynamically stable patients, or for hemodynamically unstable patients continuous venovenous hemodiafiltration at 20ml/kg/hour or sustained low-efficiency dialysis of 3-times per week. All dialysis and replacement fluids prescribed will utilize bicarbonate-buffered fluids with the electrolyte composition prescribed by the treating physician to meet the needs of the patient. The primary study end-point will be 60-day all cause mortality.

The secondary objectives of the protocol are to evaluate if intensive renal support in critically ill patients with acute renal failure will shorten the duration of ARF and decrease the incidence and duration of non-renal complications as compared to conventional support. Secondary study end-points will include all-cause hospital mortality, 1-year all cause mortality, and recovery of renal function. In addition, duration of renal support, ICU and hospital length of stay, discharges not requiring dialysis, and the development and/or recovery of non-renal organ failure during renal support will be assessed.

## **Study Size and Duration:**

The study will be conducted with a three-year intake period in order to enroll a minimum of 1164 patients. Protocol therapy will be continued for a maximum of 28 days at which time renal replacement therapy will be continued, if necessary, off of the study protocol by their treatment team. Primary follow-up for patients will be continued through day 60 for an overall study duration of 38 months.

Secondary follow-up will be performed at 1-year by telephone or mail.

A 1:1 randomization to the two treatment arms will occur with stratification of randomization by site, presence or absence of oliguria and cardiovascular SOFA organ system score. Both VA and non-VA sites will participate in the study. The study has been jointly funded through the Veterans Affairs Cooperative Studies Research Program (VACSP) and the National Institute of Diabetes, Digestive and Kidney Diseases (NIH/NIDDK).

## **Study Drugs:**

Two commercially available bicarbonate-buffered dialysate solutions, PrismaSate™ and Normocarb™ will be considered investigational study drugs for patients enrolled in CSP #530. (See section entitled “Purpose for the IND” for a full explanation of why these are investigational study drugs.) These solutions may be used as dialysate **and** replacement fluids for patients who require continuous renal replacement therapy who are enrolled in CSP #530.

CSP #530 does not require the use of PrismaSate™ and Normocarb™ either as a dialysate or replacement fluid. The study protocol only specifies that ‘all dialysis and replacement fluids prescribed utilize bicarbonate-buffered fluids with the electrolyte composition prescribed by the treating physician to meet the needs of the patient’. While it is felt that the use of the commercially available solutions has some advantages, participating sites may compound solutions to meet the physician’s individual prescription for the patient.

Due to weight and shipping considerations, the Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC) will not provide PrismaSate™ and Normocarb™ directly to participating study sites. Sites will need to order the solution(s) they plan to use through their normal purchasing/contracting mechanisms. Assistance in contracting is available through the CSPCRPCC if needed. PrismaSate™ and Normocarb™ used to treat patients enrolled in CSP #530 will be offered at a reduced cost through a rebate program that has been arranged through the manufacturers.

Sites will use drug accountability documentation (see example in section IV entitled “Drug Accountability”) provided by the CSPCRPCC to record how much PrismaSate™ and Normocarb™ was used in study patients. Rebates for the amount of dialysate/replacement fluids used will be calculated using the drug accountability documentation on a quarterly basis. The rebate will be calculated on the difference between the contract price at the facility and the special study price multiplied by the number of bags/bottles used in study patients.

Since these products are commercially available, solutions for study patients do not need to be maintained separately from commercial supplies as long as they are appropriately stored and controlled to meet all federal and state (when applicable) drug regulations and VA policies (when applicable). Additional details on this are provided below.

### **Purpose for the IND:**

CSP #530 is operating under Investigational New Drug (IND) Application Number 67,631 with the Food and Drug Administration (FDA). The IND went into effect July 26, 2003. The VA Cooperative Studies Program is the sponsor for the IND.

The purpose for the IND application with the FDA is to allow the administration of the two commercially available bicarbonate-buffered dialysate solutions, PrismaSate™ and Normocarb™, both as sterile dialysate **and** replacement fluids in patients requiring continuous renal replacement therapy. These two commercially available bicarbonate-buffered solutions are currently approved through the FDA only as sterile dialysate for continuous hemodialysis and are not approved as replacement fluids in the United States. These solutions may be used in CSP #530 via both routes of administration in hemodynamically unstable patients receiving continuous renal replacement therapy. It is this FDA non-approved route of administration that required an IND be filed.

### **Use of VA Form 10-9012 (Investigational Drug Information Record):**

CSP #530 is not designed to evaluate the different modalities of renal replacement therapy or the effectiveness of the bicarbonate-buffered dialysis and renal replacement fluids. As a result, an Investigational Drug Information Record (VA Form 10-9012) is not required for the PrismaSate™ and Normocarb™.

If your site is a VA and requests the use of a VA Form 10-9012, Investigational Drug Information Record, please contact the CSPCRPCC and a copy of a partially completed VA 10-9012 will be sent to your site for use.

## **B. Drug Treatment and Handling Procedures**

---

### **Introduction and Purpose:**

This Drug Treatment and Handling Procedures (DTHP) describe the procedures to be used by the Pharmacy, Nursing and other study personnel in handling the investigational dialysis/replacement solutions involved in this study. The DTHP forms are to be used to maintain a record of study solutions dispensed by the participating site.

### **Responsibilities of the VA Pharmacy Service:**

If you are a participating VA site, VA regulations require the Pharmacy Service to have custody of all investigational drug products and supplies, unless the responsibility has been delegated elsewhere. While PrismaSate™ and Normocarb™ are commercially available sterile dialysate solutions, these solutions must be labeled as investigational products in CSP #530. PrismaSate™ and Normocarb™ in CSP #530 are considered investigational products because they can be used as replacement fluids for continuous renal replacement therapies.

Participating VAs need to contact Pharmacy Service to discuss the custody arrangements for the dialysis/replacement fluids. VAs that decide custody of the investigational dialysate/replacement solution will be the responsibility of someone other than Pharmacy Service, must submit written authorization from the Chief of Pharmacy Service to the Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC) prior to patient enrollment in the study.

### **The address used for this correspondence is:**

Kathy Swanson, M.S., R.Ph.  
Clinical Research Pharmacist  
CSPCRPCC  
2401 Centre Ave. SE  
Albuquerque, NM 87106-4180  
(505) 248-3203  
Fax (505) 248-3205

## Responsibilities of the Investigator:

The principle investigator at the site is responsible for:

1. Completing the FDA Form 1572. The completed and signed Statement of Investigator (FDA Form 1572) must be returned to the CSPCRPCC prior to enrolling patients. Investigators need to understand and accept all commitments outlined on the FDA Form 1572.

**Note: All principle investigators must complete a FDA Form 1572 even if they do not plan to use PrismaSate™ or Normocarb™ since the study is being conducted under an IND.**

2. Providing a curriculum vitae (CV). A copy of the curriculum vitae should be attached to the FDA Form 1572.

The FDA Form 1572 and curriculum vitae can be faxed or mailed to:

Kathy Swanson, M.S., R.Ph.  
Clinical Research Pharmacist  
CSPCRPCC  
2401 Centre Ave. SE  
Albuquerque, NM 87106-4180  
(505) 248-3203  
Fax (505) 248-3205

3. Maintaining and retaining all study related documents until notified by the West Haven Coordinating Center. Adequate records of the disposition of solutions labeled for investigational use (Drug Accountability documentation), including dates, quantity and use by subject is required. Additional discussion of the Drug Accountability documentation is provided in section IV.
4. Ensuring all IRB policies are met and documents are included in the patients' medical record as required.
5. Ensuring a copy of the signed informed consent form for each patient enrolled in the study is completed and maintained.

6. Ensuring that he/she and any sub-investigators will not represent that the investigational solutions for dialysis/replacement, PrismaSate<sup>TM</sup> and Normocarb<sup>TM</sup>, used during continuous renal replacement therapy is safe and effective for the purposes being used. While published medical literature indicates the product is safe, currently there is no FDA approved indication for these products as replacement fluids. The FDA has insufficient information on file to support safety and effectiveness of these solutions as replacement fluids in continuous renal replacement therapy.
  
7. Administering dialysate/replacement solutions labeled for investigational use should occur only to subjects enrolled in the trial and who are under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.

**Description of Dialysis/Replacement Solutions:**

Generic Name or Common Name	Dialysis Solutions for Continuous Renal Replacement Therapy Ready to Use Sterile Dialysate	Sterile Bicarbonate Renal Dialysis Concentrate
Trade Name	PrismaSate™	Normocarb™
Manufacturer	Gambro Renal Products, Inc. 10810 W. Collins Avenue Lakewood, CO 80215	Dialysis Solutions, Inc. 380 Elgin Mills Road East Richmond, Hill Ontario Canada L4C 5H2
Active Ingredients	Sodium 140mEq/L Calcium 0-3.5mEq/L Potassium 0-2mEq/L Magnesium 1mEq/L Bicarbonate 32mEq/L Lactate 3mEq/L Acetate 0mEq/L Dextrose 0-1.1g/L	Sodium 140mEq/L Calcium 0mEq/L Potassium 0mEq/L Magnesium 1.5mEq/L Bicarbonate 35mEq/L Lactate 0mEq/L Acetate 0mEq/L Dextrose 0g/L
FDA's Product (Device) Classification	Dialysate Concentrate for Hemodialysis	Dialysate Concentrate for Hemodialysis
510(k) Number	K013448	K001059
Structural Formula	NA	NA
Formulation	Two-compartment terminally sterilized bag. Compartment A contains the electrolyte solution and compartment B contains the buffer solution. The two compartments are mixed immediately prior to use to produce 5 liters of sterile fluid.	240ml sterile concentrate injected into 3 liters of sterile water to produce 3.24 liters of sterile, pyrogen free fluid.
Route of Administration	Approved as a device for continuous renal replacement therapy. For this investigational plan, the sterile solution will be administered as a 1:1 ratio of dialysate and replacement fluid during continuous venovenous hemodiafiltration.	Approved as a device for continuous renal replacement therapy. For this investigational plan, the sterile solution will be administered as a 1:1 ratio of dialysate and replacement fluid during continuous venovenous hemodiafiltration.

## **Ordering Dialysis/Replacement Solutions and Costs Associated with Their Use:**

### **Ordering Solutions:**

PrismaSate™ and Normocarb™ will not be supplied directly from the CSPCRPCC. These solutions are commercially available and should be ordered through the standard mechanisms used at your site to order dialysis solutions, drugs or investigational products, whichever applies. If your site does not currently have a contractual relationship with the companies manufacturing PrismaSate™ and/or Normocarb™ the CSPCRPCC can assist in establishing a contract.

### **Costs for Dialysis/Replacement Solutions:**

The cost for the additional dialysis/replacement fluids used in patients randomized to the intensive renal support arm of the protocol is included in the site study budgets. These monies are being distributed through the West Haven Coordinating Center. The total costs associated with the use of PrismaSate™ or Normocarb™ is not included in the study budget.

In addition, sites that use PrismaSate™ or Normocarb™ as the bicarbonate-buffered solutions will be eligible for a quarterly rebate for each bag/bottle of solution used in study patients. The rebate will be calculated using information from the drug accountability documentation. (For additional information see section IV on Drug Accountability.) Rebates will be coordinated through the CSPCRPCC and the West Haven Coordinating Center.

## **Storage, Stability and Handling of Dialysis/Replacement Solutions:**

### **Information for PrismaSate™:**

#### Storage:

PrismaSate™ should be stored to meet all applicable federal, state and VA regulations. Do not store the solution below +4°C/39°F.

#### Stability:

PrismaSate™ should not be used beyond the expiration date shown on the label and the packaging. The shelf life for the solution prior to reconstitution is 12- months from the date of manufacture.

Once the over-wrap on the bag is removed, the solution should be used immediately. Stability of the product after mixing compartment A and Compartment B is 24 hours including the duration of the treatment. The solutions should not be used unless the solution is clear, free from particulate matter and all seals are intact.

Handling:

PrismaSate™ must be reconstituted and labeled immediately prior to use. PrismaSate™ comes as a 5-liter latex free PVC two-compartment bag. Compartment A, the smaller compartment, contains the electrolyte solution and compartment B, contains the buffer solution. Final reconstitution is obtained by using the five-step process outlined on the following page.

Information on PrismaSate™ five-step process appears on the next page.

# How to use PrismaSate™

## Five Easy Steps

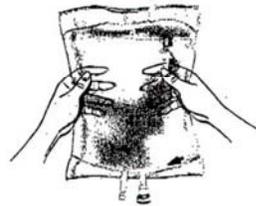
1. Break the red frangible pin between the two compartments.



2. Transfer all fluid from the small compartment (A) into the large one.



3. Rinse the small compartment twice by pressing the mixed solution from the large compartment back and forth between the two compartments.



4. When the small compartment is empty, shake large compartment to mix completely. The solution is now ready to use.



5. Either spike the access port or connect the luer lock to luer access port and break the clear frangible pin.



## GAMBRO Renal Products

10810 West Collins Avenue  
Lakewood, CO 80215-4439  
800-525-2623 or 303-232-6800  
visit us at [www.usa-gambro.com](http://www.usa-gambro.com)

Caution: Federal Law (USA) restricts this device to sale by, or on the order of, a physician.  
Read Instructions for Use prior to patient application.  
Trademarks used herein are owned by or licensed to Gambro, Inc.  
©2003 Gambro, Inc. Printed in the USA 1/03 305100075 FWH A

## **Information for Normocarb™:**

### Storage:

Normocarb™ should be stored to meet all applicable federal, state and VA regulations. The undiluted concentrate may be stored at normal room temperature. The concentrate should not be frozen. Once reconstituted, the solution may be stored at room temperature or refrigerated (2°-30°C). The reconstituted solution should not be frozen or exposed to excessive heat.

### Stability:

Normocarb™ should not be used beyond the expiration date shown on the label. Once Normocarb™ is diluted, the solution should be used within 24 hours. The concentrate and diluted solutions should not be used unless they are clear, free from precipitate, and all seals are intact.

### Handling:

Normocarb™ must be diluted before use. Normocarb™ comes as a 240 ml clear, sterile, nonpyrogenic, concentrate in glass vials. For dilution, one 240 ml glass vial of Normocarb™ should be added to 3-liters of sterile water to make 3.24L of solution. Normocarb™ must be diluted with sterile water. Do not use normal saline, lactated ringers or any diluents other than sterile water.

### Items needed for reconstitution:

- 1 vial Normocarb™
- 1-vented IV transfer set
- 1 20 G needle
- 3 liters of sterile water
- Alcohol swabs

Remove sterile water from outer protective wrapper and wipe injection port on bag with alcohol swab. Use aseptic technique. Assemble IV line, needle and close clamp. Spike vial and connect needle to bag. Hang vial above the level of the sterile water. Open clamp and empty contents of the 240 ml glass vial of Normocarb™ into the 3-liters of sterile water to make a 3.24-liter solution. Clamp and remove transfer set from 3.24-liter solution. Shake to mix contents by rocking or rolling bag and contents thoroughly.

Normocarb™ is physically and chemically compatible with a wide variety of diluents. For patients requiring dextrose, 12 ml of D50W may be added to the 3.24-liter bag of diluted Normocarb™ to make a final concentration of dextrose of 10.2 mEq/L. Potassium chloride up to 4mEq/L and calcium chloride up to 2.5mEq/L (1.25mMol/L) may be added to the diluted solution.

## **Dispensing Dialysis/Replacement Solutions:**

These products can only be dispensed on the order of a physician or properly licensed practitioner.

## **Labeling Dialysis/Replacement Solutions:**

The bags of PrismaSate™ and Normocarb™ used for patients enrolled in CSP #530 must bear an investigational label bearing the statement “Caution: New Drug – Limited by Federal (or United States) law to investigational use.” The label may not bear any statement that is false or misleading and shall not represent the investigational solution as safe or effective for the purpose it is being used.

Due to stability concerns, the labels cannot be affixed to the solutions until just prior to use. Labels should be affixed to bags of solutions used for both dialysis and replacement fluids. The “Investigational Drug” labels are two part labels. One part of the “Investigational Drug” label (left side) should be placed directly on the PVC bag containing the PrismaSate™ or Normocarb™. Labels should not be fixed to the outer wrapping of the PVC bag or the glass vial containing the undiluted Normocarb™. The second part of the label (right side) is affixed to the Drug Accountability documentation. (Additional information on drug accountability is provided in Section IV.)

Sites may also affix a pharmacy or facility label to the solutions to meet local labeling requirements and indicate if additional additives have been used.

No special labels are required for the dialysate/replacement fluids in study patients if the facility does not treat patients with PrismaSate™ or Normocarb™.

## **Ordering “Investigational Drug” Labels:**

A supply of preprinted labels bearing the “Investigational Drug” statement, the study name, study site number, and name of the product will be provided to all sites through the CSPCRPCC. An initial shipment of labels will be provided to sites once the FDA Form 1572 has been completed. Label supplies can be reordered through the CSPCRPCC by either sending an E-mail, calling or faxing a request to:

Kathy Swanson, M.S., R.Ph.  
Clinical Research Pharmacist  
CSPCRPCC (151-I)  
2401 Centre Ave. SE  
Albuquerque, NM 87106-4180  
(505) 248-3203 Fax (505) 248-3205  
E-mail: [Kathy.Swanson@csp.research.med.va.gov](mailto:Kathy.Swanson@csp.research.med.va.gov)

Example of FDA approved label to be inserted on page here.

## C. Drug Information

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PrismaSate™ and Normocarb™ are licensed in the United States as devices by the Food and Drug Administration (FDA) for hemodialysis. The manufacturer's information provided below reflects this approved and labeled indication.

Official packaging materials available on pages on the following pages.

# PRISMASATE

## INSTRUCTIONS FOR USE

PrismaSate™ DIALYSIS SOLUTION FOR CONTINUOUS RENAL REPLACEMENT THERAPY

### READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS SOLUTION

Keep this leaflet. You may need to read it again.

### WHAT DOES PrismaSate CONTAIN?

PrismaSate is presented in a two compartment bag containing in the smaller compartment A, an electrolyte solution, and in the larger compartment B, a buffer solution. Contents of each solution is described on the bag.

The final reconstituted solution is obtained after breaking the frangible pin and mixing both solutions. Refer to bag labeling for composition of the final reconstituted solution.

**PACKAGING:**  
2 bags (5000 mL) per carton.

### WHAT IS PrismaSate AND WHAT IS IT USED FOR?

PrismaSate is a solution for use as a dialysate in Continuous Renal Replacement Therapies, such as continuous hemodialysis and hemodiafiltration aimed at normalizing the composition of the blood.

PrismaSate is a solution packed in a two-compartment bag. The electrolyte solution (in the small compartment A) must be mixed with the buffer solution (in the large compartment B) before use to obtain the final solution suitable for the treatment.

PrismaSate is used in the treatment of acute kidney disease (renal failure), as a dialysis solution in Continuous Renal Replacement Therapy.

PrismaSate may also be used in case of drug poisoning with dialyzable or filterable substances.

PrismaSate should only be used by or under the direction of a physician competent in intensive care treatment using Continuous Renal Replacement Therapy.

Federal Law (USA) restricts this device to sale by or on the order of a physician.

### WHAT SIDE EFFECTS CAN PrismaSate CAUSE?

When continuous hemodialysis and hemodiafiltration are performed correctly, side effects are uncommon.

The content of the fluid is similar to that of blood and the quantity of fluid used is controlled.

Some side effects may occur, including nausea, vomiting, muscle cramps and low blood pressure (hypotension).

### STORAGE AND EXPIRY DATE

Do not use after the expiry date shown on the label and the packaging.

Use only if the solution is clear and all seals are intact.

Do not store below +4°C/39°F.

From a chemical point of view, once opened, the product should be used immediately. Stability of the product after reconstitution is 24 hours including the duration of the treatment. Other in-use storage times and conditions are the responsibility of the user.

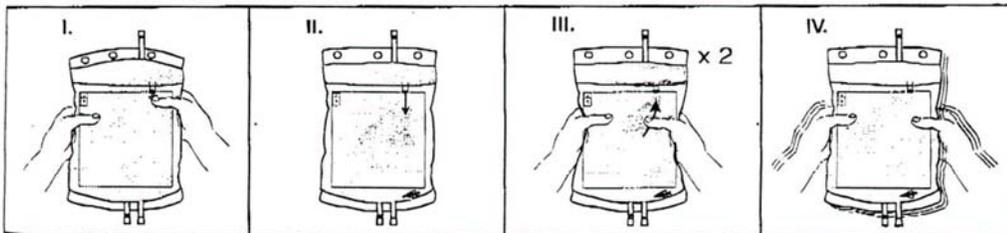
### INSTRUCTION FOR USE AND HANDLING:

**I** Remove the over-wrap from the bag immediately before use and discard any other packaging materials. Open the seal by breaking the frangible-pin between the two compartments of the bag. The frangible-pin will remain in the bag.

**II** Make sure all the fluid from the small compartment A is transferred into the large compartment B.

**III** Rinse the small compartment A **twice** by pressing the mixed solution back into the small compartment A and then back into the large compartment B.

**IV** When the small compartment A is empty: shake the large compartment B so that contents mix completely. The solution is now ready to use. The bag should hang in all three hanging holes when used.



Gambro Renal Products. 10810 West Collins Avenue. Lakewood, CO 80215. 1-800-651-2823

**A**  
**B**

# PRISMASATE

BGK2/0

Dialysis Solution for Continuous Renal Replacement Therapy  
Solución de diálisis para la terapia de sustitución renal continua

2 K<sup>+</sup>  
0 Ca<sup>2+</sup>  
110 Glu

Each 1000 mL contains/Cada 1000 mL contiene:								
<b>Before reconstitution/Antes de reconstituir el producto</b>								
	<b>A</b>		<b>B</b>					
	250 mL		4750 mL					
Magnesium chloride/Cloruro de magnesio, 8 H <sub>2</sub> O	2.033 g							
Glucose anhydrous/Glucose anhidra	22.00 g							
Sodium chloride/Cloruro de sodio			8.45 g					
Potassium chloride/Cloruro de potasio			0.157 g					
Lactic acid/Ácido láctico	5.400 g							
Sodium bicarbonate/Bicarbonato de sodio			3.090 g					
Water for injections q. s. ad/Agua inyectable cbp	1000 mL		1000 mL					
<b>After reconstitution/Después de reconstituir A + B</b>								
	Calcium Ca <sup>2+</sup>	Magnesium Mg <sup>2+</sup>	Sodium Na <sup>+</sup>	Chloride Cl <sup>-</sup>	Lactate	Bicarbonate HCO <sub>3</sub> <sup>-</sup>	Potassium K <sup>+</sup>	Glucose
mmol/L	0	0.5	140	108	3	32	2	6.1
mEq/L	0	1.0	140	108	3	32	2	(110 mg/dL)
Theoretical osmolality/Osmolaridad teórica: 292 mOsm/L								
<p><b>Mix both compartments before use.</b> See instructions for Use for further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. Any unused portion must be discarded. See instructions for Use for shelf life of reconstituted solution. Federal Law (USA) restricts this device to sale by or on the order of a physician. <b>Not for direct infusion.</b></p>				<p><b>Antes de usar mezclar ambos compartimentos.</b> Consulte las instrucciones completas en el folleto adjunto. Este producto ha sido esterilizado y se encuentra libre de endotoxinas bacterianas. Verifique que la bolsa está intacta. Use el producto sólo si la solución es transparente. Este producto es para un solo uso. Deschete la solución sobrante. Consulte las instrucciones de uso para la vida de anaquel de la solución reconstituida. Las leyes federales de los Estados Unidos restringen a venta de este producto al médico o por prescripción médica. <b>Este producto no está indicado para infusión directa.</b></p>				

5000 INFORMATIONAL COPY  
GAMBRO.

Product code: D07000002  
Batch No. and expiry date are printed on the back of the bag.  
Do not store below +4°C/39°F.  
Número de lote y fecha de caducidad impresos en la parte posterior de la bolsa. No conservar a temperaturas inferiores a +4°C/39°F.  
Gambro Renal Products, 10810 West Collins Avenue, Lakewood, CO 80215  
Manufactured by/Fabricado por: Gambro Renal Products, Biosol S.p.A., SS Stevio km 86.4, IT-23035 SONDALLO (SO) ITALY

D0720000 Rev. 2002-05

Prismasate BGK2/0 Bag

1

C2-06-13, CR.51

**2 K<sup>+</sup>**  
**0 Ca<sup>2+</sup>**  
**110 Glu**

**PRISMASATE**  
BGK2/0

Dialysis Solution for Continuous Renal Replacement Therapy  
Solución de diálisis para la terapia de sustitución renal continua

<b>A</b>	<b>B</b>
----------	----------

Each 1000 mL contains/Cada 1000 mL contiene:

Before reconstitution/ Antes de reconstituir	A	B
Magnesium chloride/Cloruro de magnesio, 6 H <sub>2</sub> O	250 mL	4750 mL
Glucose anhydrous/Glucosa anhidra	2.033 g	
Sodium chloride/Cloruro de sodio	22.00 g	8.45 g
Potassium chloride/Cloruro de potasio		0.157 g
Lactic acid/Ácido láctico	5.400 g	
Sodium bicarbonate/Bicarbonato de sodio		3.090 g
Water for injections q.s. ad/Agua inyectable cbp	1000 mL	1000 mL
<b>After reconstitution/Después de reconstituir, A + B</b>		
Calcium Ca <sup>2+</sup>	mmol/L	0
Magnesium Mg <sup>2+</sup>	mmol/L	0.5
Sodium Na <sup>+</sup>	mmol/L	140
Chloride Cl <sup>-</sup>	mmol/L	108
Lactate Lactate	mmol/L	3
Bicarbonate HCO <sub>3</sub> <sup>-</sup>	mmol/L	32
Potassium K <sup>+</sup>	mmol/L	2
Glucose	mg/dL	6.1
Theoretical osmolality/Osmolaridad teórica:		292 mOsm/L

Mix both compartments before use. See instructions for use for further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. Any unused portion must be discarded. See Instructions for Use for shelf life of reconstituted solution. Federal Law (USA) restricts this device to sale by or on the order of a physician. Do not store below +4°C/39°F. Not for direct infusion.

Antes de usar, mezclar ambos compartimientos. Consulte las instrucciones completas en el folleto adjunto. Este producto ha sido esterilizado y se encuentra libre de endotoxinas bacterianas. Verifique que la bolsa está intacta. Use el producto sólo si la solución es transparente. Este producto es para un solo uso. Después de la solución se restringe la venta de este producto al médico o por prescripción médica. No conservar a temperaturas inferiores a +4°C/39°F. Este producto no está indicado para infusión directa.

Product code: D07000002

Batch No./  
Número de lote:

Expiry date/  
Fecha de caducidad:

INFORMATIONAL COPY



Primasate BGK2/0 Box

07-05-13, 16:45

**A**  
**B**

# PRISMASATE

BK0/3.5

Dialysis Solution for Continuous Renal Replacement Therapy  
Solución de diálisis para la terapia de sustitución renal continua

0 K<sup>+</sup>  
3.5 Ca<sup>2+</sup>  
0 Glu

Each 1000 mL contains/Cada 1000 mL contienen:							
Before reconstitution/Antes de reconstituir el producto							
				A	B		
				260 mL	4760 mL		
Calcium chloride/Cloruro de calcio, 2 H <sub>2</sub> O				5.145 g			
Magnesium chloride/Cloruro de magnesio, 6 H <sub>2</sub> O				2.033 g			
Sodium chloride/Cloruro de sodio					8.45 g		
Lactic acid/Ácido láctico				5.400 g			
Sodium bicarbonate/Bicarbonato de sodio					3.090 g		
Water for injections q.s. ad/Agua inyectable cbb				1000 mL	1000 mL		
After reconstitution/Después de reconstituir A + B							
Calcium	Magnesium	Sodium	Chloride	Lactate	Bicarbonate	Potassium	Glucose
Ca <sup>2+</sup>	Mg <sup>2+</sup>	Na <sup>+</sup>	Cl <sup>-</sup>		HCO <sub>3</sub> <sup>-</sup>	K <sup>+</sup>	
mmol/L 1.75	0.5	140	109.5	3	32	0	0
mEq/L 3.5	1.0	140	109.5	3	32	0	0
Theoretical osmolality/Osmolalidad teórica: 287 mOsm/L							

Mix both compartments before use. See instructions for Use for further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. Any unused portion must be discarded. See instructions for Use for shelf life of reconstituted solution. Federal Law (USA) restricts this device to use by or on the order of a physician. Not for direct infusion.

Antes de usar mezclar ambos compartimentos. Consulte las instrucciones completas en el folleto adjunto. Este producto ha sido esterilizado y se encuentra libre de endotoxinas bacterianas. Verifique que la bolsa esté intacta. Use el producto sólo si la solución es transparente. Este producto es para un solo uso. Deséchelo la solución sobrante. Mezcle los dos componentes antes de usar el producto. Consulte las instrucciones de uso para la vida de anaquel de la solución reconstituida. Las leyes federales de los Estados Unidos restringen a venta de este producto al médico o por prescripción médica. Este producto no está indicado para infusión directa.

**5000 mL INFORMATIONAL COPY**  
**GAMBRO**

CoE code: D07000001 EAN-14: 07332614037031 Catalog# 6054351

Batch No. and expiry date are printed on the back of the bag. Do not store below +4°C/39°F. Número de lote y fecha de caducidad impresos en la parte posterior de la bolsa. No conservar a temperaturas inferiores a +4°C/39°F. Gambro Renal Products, 10810 West Collins Avenue, Lakewood, CO 80215. Manufactured by/Fabricado por: Gambro Renal Products, Biorol S.p.A., SS Strivio km 86.4, IT-23035 SONDALO (SO) ITALY

Prismasate BK0/3.5 Bag

1

03-02-05, 10 44

00700001 Rev. 2003-01

# PRISMASATE

**A** **B**

0 K<sup>+</sup>  
3.5 Ca<sup>2+</sup>  
0 Glu

BK03.5

Dialysis Solution for Continuous Renal Replacement Therapy  
Solución de diálisis para la terapia de sustitución renal continua

Each 1000 mL contains/Cada 1000 mL contiene:	
Before reconstitution/ Antes de reconstituir	A B 250 mL 4750 mL
Calcium chloride/Cloruro de calcio, 2 H <sub>2</sub> O	5.145 g
Magnesium chloride/Cloruro de magnesio, 6 H <sub>2</sub> O	2.033 g
Sodium chloride/Cloruro de sodio	6.45 g
Lactic acid/Ácido láctico	5.400 g
Sodium bicarbonate/Bicarbonato de sodio	3.050 g
Water for injections q.s. ad/Agua inyectable cbp	1000 mL
After reconstitution/Después de reconstituir, A + B	
Calcium Ca <sup>2+</sup>	1.75
Magnesium Mg <sup>2+</sup>	0.5
Sodium Na <sup>+</sup>	140
Chloride Cl <sup>-</sup>	109.5
Lactate C <sub>3</sub> H <sub>5</sub> O <sub>2</sub> <sup>-</sup>	3
Bicarbonate HCO <sub>3</sub> <sup>-</sup>	3
Glucose	0
Potassium K <sup>+</sup>	0
Theoretical osmolality/Osmolaridad teórica	287 mOsm/L

**Mix both compartments before use.**  
See instructions for use for further instructions. Sterile and free from bacterial endotoxins. Confirm the integrity of the packaging. Use only if solution is clear. For single use only. Any unused portion must be discarded. See instructions for use for shelf life of reconstituted solution. Federal Law (USA) restricts this device to sale by or on the order of a physician. Do not store below +4°C/39°F. Not for direct infusion.

**Antes de usar, mezclar ambos compartimentos.**  
Consulte las instrucciones completas en el folleto adjunto. Este producto ha sido esterilizado y se encuentra libre de endotoxinas bacterianas. Verifique que la bolsa esté intacta. Use el producto sólo si la solución es transparente. Este producto es para un solo uso. Deséchela la solución sobrante. Mezcle los dos componentes antes de usar el producto. Consulte las instrucciones de uso para la vida de anaquel de la solución reconstituida. Las leyes federales de los Estados Unidos restringen la venta de este producto al médico o por prescripción médica. No conservar a temperaturas inferiores a +4°C/39°F. Este producto no está indicado para infusión directa.

Castrol® 6054351

CoE code: D07000001 EAN-14: 3733241407031

LOT: [ ] Batch No./  
Número de lote:

Expiry date/  
Fecha de caducidad:



Primasate BK03.5 Box

03/02/01, 10-46

0740001 Rev. 2003-01



## NORMOCARB™ Sterile Bicarbonate Renal Dialysis Concentrate

### PRODUCT INFORMATION

**THERAPEUTIC CLASSIFICATION:** Dialysate concentrate for hemodialysis.

**INDICATIONS AND USAGE:** NORMOCARB™ is indicated for use in Continuous Renal Replacement Therapy (CRRT). NOT FOR INFUSION. DILUTE WITH STERILE WATER BEFORE USE. Do not use except on the order of a physician.

**COMPATIBILITY:** NORMOCARB™ is physically and chemically compatible with a wide variety of diluents. HOWEVER, FOR USE IN DIALYSIS, NORMOCARB™ MUST BE DILUTED WITH STERILE WATER. DO NOT USE NORMAL SALINE, RINGERS LACTATE OR ANY DILUENT OTHER THAN STERILE WATER. NORMOCARB™ is compatible with all systems used for CRRT.

**STABILITY AND STORAGE RECOMMENDATIONS:** NORMOCARB™ (Undiluted): Store at normal room temperature (15°-30°C). Do not freeze. Do not use if a precipitate has formed or if container seals have been damaged. **Dialysate Solution [NORMOCARB™ (Diluted)]:** Because bicarbonate is lost through most plastics used to make diluent bags, once prepared, the dialysate solution (diluted NORMOCARB™) should be used within 24 hours. It may be stored at normal room temperature or refrigerated (2°-30°C). Do not freeze dialysate or expose to excessive heat.

**INSTRUCTIONS FOR USE:** Using aseptic technique, add contents of one 240 mL vial to a 3 L bag of sterile water to make 3.24 L dialysate solution. Shake to mix by rocking or rolling the bag and contents thoroughly. Connect bag to CRRT circuit.

For patients requiring dextrose, D50W may be added to the dialysate according to physician's orders (see RECONSTITUTION below for detailed instructions).

#### RECONSTITUTION (PREPARATION OF DIALYSATE SOLUTION USING NORMOCARB™ AND STERILE WATER):

##### Requirements:

- NORMOCARB™, 1 vented IV transfer set, 1 20 G needle
- 3 L of sterile water
- Alcohol swabs

**Important Considerations Before Reconstitution:** NORMOCARB™ must be diluted before use with sterile water only -- do not use normal saline, Ringers Lactate or any other diluent. D50W may be added to sterile water, if required by physician's orders, as described in the method below. Do not prepare more dialysate than can be used in a 24-hour period.

##### Method:

- 1) Remove bag of sterile water from outer protective bag and wipe injection port on bag with alcohol swab.
- 2) Using aseptic technique:
  - a) Assemble IV line, needle, and close clamp
  - b) Spike vial
  - c) Connect needle to bag
- 3) Using vial hanger, hang vial from IV pole.
- 4) Open clamp and empty contents of one 240 mL NORMOCARB™ vial into a 3 L bag of sterile water to make 3.24 L of dialysate.
- 5) **Special Consideration:** For patients requiring dextrose, 12 mL of D50W may also be added to the bag of sterile water to make 3.25 L of dialysate, with a concentration of dextrose of 10.2 mEq/L according to physician's orders.
- 6) Clamp IV line.
- 7) Complete "Medication Added" sticker with required information and apply to bag.
- 8) Disconnect needle and IV set.
- 9) Shake to mix by rocking or rolling the bag and contents thoroughly. When diluted, solution contains approximately (mEq/L):  
Na 140, Mg 1.5, Cl 106.5, HCO<sub>3</sub> 35.0
- 10) Connect bag to CRRT dialysis circuit and institute dialysis.

**DOSAGE AND ADMINISTRATION:** Usual dialysate flow rate is 1000 to 2000 mL/hr or 20 mL/kg/hr for adults and 2 L/1.73 m<sup>2</sup>/hr for children. Refer to Prescribing Information leaflet for full details. Available to physicians and pharmacists upon request.

129908

March 2001

DIALYSIS SOLUTIONS INC., 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2 Tel: (905) 884-6296



## NORMOCARB™ Sterile Bicarbonate Renal Dialysis Concentrate

ESSENTIAL PRESCRIBING INFORMATION  
July 2001

### THERAPEUTIC CLASSIFICATION

Dialysate Concentrate for Hemodialysis.

### DEVICE DESCRIPTION

A clear, sterile, nonpyrogenic, calcium-free bicarbonate renal dialysis concentrate.

### Composition:

**NORMOCARB™ (Undiluted):** NORMOCARB™ contains 82.84 g/L sodium chloride (NaCl), 2.06 g/L magnesium chloride (MgCl<sub>2</sub>) and 39.7 g/L sodium bicarbonate (NaHCO<sub>3</sub>) in water for injection.

**Dialysate Solution (NORMOCARB™ (Diluted):** The dialysate solution (diluted NORMOCARB™), when prepared as directed, contains the following:

Component	Concentration	
	(mMol/L)	(mEq/L)
Sodium (Na)	140.0	140.0
Magnesium (Mg)	0.75	1.5
Chloride (Cl)	106.5	106.5
Bicarbonate (HCO <sub>3</sub> )	35.0	35.0
Total Anions	141.5	mEq/L
Total Cations	141.5	mEq/L

The nominal measured final conductivity of the dialysate solution is 140 mmhos/cm at 25°C.

If required in patients on insulin or with hypoglycemia, 12 mL of D50W may be added to the sterile water when preparing the dialysate to provide a concentration of 10.2 mEq/L of dextrose in the diluted solution.

Potassium chloride may be added by physician's orders, usually up to 4 mEq/L. Calcium chloride [up to 1.25 mMol/L (2.5 mEq/L)] may be added to the diluted solution by physician's orders.

### INTENDED USE/INDICATIONS

NORMOCARB™, after dilution, is indicated for use in Continuous Renal Replacement Therapy (CRRT).

Continuous renal replacement therapy is a dialysis continued 24 hours a day to treat critically ill patients with renal failure. NORMOCARB™ is not approved for infusion.

CRRT is usually administered to patients in intensive care who require dialysis and are hemodynamically unstable, or whose liver function is either impaired or at risk of impairment. Patients with liver impairment typically are more challenging to manage and may have high requirements for bicarbonate due to ongoing lactic acidosis. Use of lactate-based solutions for dialysis may not correct metabolic acidosis if the liver cannot metabolize more lactate into bicarbonate. The bicarbonate-free lactate-containing dialysis solution will actually remove some bicarbonate from the patient. In addition to a bicarbonate-based dialysis solution, patients with liver impairment and/or severe metabolic acidosis may require additional intravenous infusions of bicarbonate to maintain their pH within acceptable parameters.

The aims of CRRT are control of fluid balance, control of plasma electrolytes, control of acid-base balance and removal of products of metabolism.

### CONTRAINDICATIONS

There are no known contraindications to the use of NORMOCARB™.

### WARNINGS AND PRECAUTIONS

**NORMOCARB™ IS NOT FOR INFUSION.**

After prolonged dialysis there is a risk of hypocalcemia and even the possibility of hypoglycemia. This can be prevented with ongoing nutrition, monitoring and replacement, if necessary.

NORMOCARB™ must be diluted with sterile water before use. **DO NOT USE NORMAL SALINE, RINGERS LACTATE OR ANY OTHER DILUENT EXCEPT STERILE WATER.**

The patient's hemodynamic, fluid, electrolyte and acid-base balance should be monitored throughout the procedure.

Since NORMOCARB™ is potassium- and calcium-free, close monitoring of the patient's potassium and calcium levels must be carried out during CRRT. It is recommended that these levels are followed twice daily or according to local CRRT protocols.

NORMOCARB™ must not be used if a precipitate has been formed or if container seals have been damaged.

NORMOCARB™ should not be used in dialysate proportioning intermittent hemodialysis machines.

### Use in Pregnancy:

No information is available on the use of NORMOCARB™ during pregnancy. Administer to pregnant women only if clearly needed and the potential benefit outweighs the potential risk.

### ADVERSE EVENTS

The most common complications during hemodialysis are, in descending order of frequency, hypotension (20 - 30%), cramps (5 - 20%), nausea and vomiting (5 - 15%), headache (5%), itching (5%), chest pain (2 - 5%), back pain (2 - 5%), and fever and chills (<1%).

Less common but serious complications observed during hemodialysis include disequilibrium syndrome, hypersensitivity reactions, arrhythmia, cardiac tamponade, intracranial bleeding, seizures, hemolysis and air embolism.

Healthcare practitioners should also be aware that dialyzer reactions may occur in patients.

#### DOSAGE AND ADMINISTRATION

**NORMOCARB™ MUST BE DILUTED BEFORE USE.** For dilution, one 240 mL vial of NORMOCARB™ should be added to 3 L of sterile water to make 3.24 L of dialysate solution. See RECONSTITUTION below for detailed instructions.

#### Individualization of Treatment:

The volume of dialysate solution (diluted NORMOCARB™) administered will depend upon the fluid balance of the individual patient, the target fluid balance to be achieved, the body weight and the amount of fluid removed from the patient's circulation during the process of dialysis. DOSAGE MUST THEREFORE BE AT THE DISCRETION OF THE PHYSICIAN.

The usual dosage range commonly used is as follows:

**Adults:** Usual dialysate flow rate is 1000 to 2000 mL/hr or 20 mL/Kg/hr.

**Children:** Usual dialysate flow rate is 2 L/1.73 m<sup>2</sup>/hr.

**Elderly:** Usual dialysate flow rate as per adults but will depend on the hemodynamic condition of the elderly patient.

For patients requiring dextrose, D50W may be added to the dialysate according to physician's orders (see RECONSTITUTION below for detailed instructions).

#### RECONSTITUTION (Preparation of Dialysate Solution Using NORMOCARB™ and Sterile Water)

##### Requirements:

- NORMOCARB™, 1 vented IV transfer set, 1 20 G needle
- 3 L of sterile water
- Alcohol swabs

##### Important Considerations Before Reconstitution:

**NORMOCARB™ must be diluted before use with sterile water only -- do not use normal saline, Ringers Lactate or any other diluent. D50W may be added to sterile water, if required by physician's orders, as described in the method below. Do not manufacture more dialysate than can be used in a 24-hour period.**

##### Method:

- 1) Remove bag of sterile water from outer protective bag and wipe injection port on bag with alcohol swab.
- 2) Using aseptic technique:
  - a) Assemble IV line, needle, and close clamp
  - b) Spike vial
  - c) Connect needle to bag
- 3) Using vial hanger, hang vial from IV pole.
- 4) Open clamp and empty contents of one 240 mL vial into a 3 L bag of sterile water to make 3.24 L of dialysate.
- 5) **Special Consideration:** For patients requiring dextrose, 12 mL of D50W may also be added to the bag of sterile water, to make 3.25 L of dialysate with a concentration of dextrose of 10.2 mEq/L according to physician's orders.
- 6) Clamp IV line.
- 7) Fill out required information on accompanying "Medication Added" sticker and apply to bag.
- 8) Disconnect needle and IV set.
- 9) Shake to mix by rocking or rolling the bag and contents thoroughly. When diluted, solution contains approximately (mEq/L): Na 140, Mg 1.5, Cl 106.5, HCO<sub>3</sub> 35.0.
- 10) Connect bag to CRRT dialysis circuit and institute dialysis.

##### COMPATIBILITY

NORMOCARB™ is physically and chemically compatible with a wide variety of diluents. HOWEVER, FOR USE IN DIALYSIS, NORMOCARB™ MUST BE DILUTED WITH STERILE WATER. DO NOT USE NORMAL SALINE, RINGERS LACTATE OR ANY DILUENT OTHER THAN STERILE WATER. NORMOCARB™ is compatible with all systems used for CRRT.

##### SYMPTOMS AND TREATMENT OF OVERDOSAGE

Overdosage with dialysate solutions should not occur if the procedure is carried out correctly and the patient's fluid, electrolyte and acid-base balance are monitored closely. After prolonged dialysis, fluid and electrolyte changes may occur including hypokalemia, volume depletion, hypophosphatemia, hypocalcemia and possibly vitamin and mineral deficiencies. Continued application of dialysis will remove excess fluid. Regular monitoring and appropriate supplementation, including nutritional supplementation, are part of standard continuous renal replacement therapy care.

##### HOW SUPPLIED

NORMOCARB™ is available as a clear, sterile, nonpyrogenic, calcium-free bicarbonate renal dialysis concentrate in single-use vials of 240 mL.

##### Storage:

**NORMOCARB™ (Undiluted):** Store at room temperature (15° - 30°C). Do not freeze. Do not use if a precipitate has formed or if container seals have been damaged.

**Dialysate Solution (NORMOCARB™ (Diluted)):** Because bicarbonate is lost through most plastics used to make diluent bags, once prepared, the dialysate solution (diluted NORMOCARB™) should be used within 24 hours. It may be stored at normal room temperature or refrigerated (2° - 30°C). Do not freeze dialysate or expose to excessive heat.

**CAUTION: Federal Law restricts this device to sale by, or on the order of, a physician (or properly licensed practitioner).**

##### Manufactured by:

Novex Pharma  
Richmond Hill, Ontario  
Canada L4C 5H2  
132059



## NORMOCARB™ Concentré de bicarbonate stérile pour dialyse rénale

### RENSEIGNEMENTS SUR LE PRODUIT

**CLASSE THÉRAPEUTIQUE:** Concentré de solution de dialyse pour l'hémodialyse.

**INDICATIONS ET UTILISATION:** NORMOCARB™ est indiqué pour le traitement de suppléance rénale continu. NON DESTINÉ À LA PERFUSION. DILUER AVEC DE L'EAU STÉRILISÉE AVANT L'UTILISATION. N'utiliser que selon les ordres du médecin.

**COMPATIBILITÉ:** NORMOCARB™ est physiquement et chimiquement compatible avec une vaste gamme de diluants. CÉPENDANT, POUR LA DIALYSE, NORMOCARB™ DOIT ÊTRE DILUÉ AVEC DE L'EAU STÉRILISÉE. NE PAS UTILISER DE SOLUTÉ PHYSIOLOGIQUE, DE LACTATE DE RINGER NI AUCUN DILUANT AUTRE QUE DE L'EAU STÉRILISÉE. NORMOCARB™ est compatible avec tous les systèmes utilisés pour le traitement de suppléance rénale continu.

**STABILITÉ ET RECOMMANDATIONS D'ENTREPOSAGE:** NORMOCARB™ (non dilué): Conserver à la température ambiante normale (15°-30°C). Ne pas congeler. Ne pas utiliser si un précipité s'est formé ou si les joints d'étanchéité du récipient ont été endommagés. **Solution de dialyse [NORMOCARB™ (dilué)]:** Comme la plupart des plastiques utilisés pour fabriquer les sacs de diluants provoquent une déperdition du bicarbonate, la solution de dialyse (NORMOCARB™ dilué) doit être utilisée dans les 24 heures suivant sa préparation. Elle peut être conservée à la température ambiante normale ou être réfrigérée (2°-30°C). Ne pas congeler la solution de dialyse ou l'exposer à une chaleur excessive.

**MODE D'EMPLOI:** Selon la technique d'asepsie, ajouter le contenu d'une fiole de 240 mL à un sac de 3 L d'eau stérilisée pour préparer 3,24 L de solution de dialyse. Secouer, pour mélanger complètement, en basculant ou en remuant le sac et le contenu. Raccorder le sac au circuit traitement de suppléance rénale continue.

Pour les patients ayant besoin de dextrose, D50W peut être ajouté à la solution de dialyse, selon les ordres du médecin (voir RECONSTITUTION ci-dessous pour les instructions détaillées).

### RECONSTITUTION (PRÉPARATION DE LA SOLUTION DE DIALYSE À L'AIDE DE NORMOCARB™ ET D'EAU STÉRILISÉE):

#### Éléments nécessaires:

- NORMOCARB™, 1 trousse de transfert intraveineux à évent, 1 aiguille 20 G
- 3 L d'eau stérilisée
- Tampons imbibés d'alcool

**Directives importantes à ne pas oublier avant la reconstitution:** NORMOCARB™ doit être dilué avant l'utilisation, avec de l'eau stérilisée seulement – ne pas utiliser de soluté physiologique, de lactate de Ringer ni aucun autre diluant. D50W peut être ajouté à l'eau stérile, si requis par les ordres du médecin, comme décrit dans la méthode ci-dessous. Ne pas préparer une quantité de solution de dialyse supérieure à la quantité nécessaire pour une période de 24 heures.

#### Méthode:

- 1) Retirer le sac d'eau stérilisée du sac protecteur extérieur et essuyer le site d'injection du sac à l'aide d'un tampon imbibé d'alcool.
- 2) Selon la technique d'asepsie:
  - a) Assembler le tube i.v. et l'aiguille, puis clamper
  - b) Perforer la fiole
  - c) Raccorder l'aiguille au sac
- 3) Suspender la fiole au crochet de la tige porte-sérum.
- 4) Ouvrir le clamp et vider le contenu d'une fiole de 240 mL de NORMOCARB™ dans un sac de 3 L d'eau stérilisée pour préparer 3,24 L de solution de dialyse.
- 5) Considération spéciale: selon les ordres du médecin, pour les patients ayant besoin de dextrose, 12 mL de D50W peuvent également être ajoutés au sac d'eau stérile pour préparer 3,25 L de solution de dialyse, avec une concentration de dextrose de 10,2 mEq/L.
- 6) Clamper le tube i.v.
- 7) Prendre l'autocollant « Médicament ajouté », y inscrire les renseignements demandés et le coller sur le sac.
- 8) Détacher l'aiguille et la trousse i.v.
- 9) Secouer, pour mélanger complètement, en basculant ou en remuant le sac et le contenu. Contenu approximatif de la solution une fois diluée (mEq/L): Na 140, Mg 1,5, Cl 106,5, HCO<sub>3</sub> 35,0
- 10) Raccorder le sac au circuit de dialyse de traitement de suppléance rénale continu et commencer la dialyse.

**POSOLOGIE ET ADMINISTRATION:** Le débit habituel de la solution de dialyse est de 1000 à 2000 mL/hr ou 20 mL/kg/hr pour les adultes et de 2 L/1,73 m<sup>2</sup>/hr pour les enfants. Voir les détails complets sur le feuillet de renseignements d'ordonnance. Disponible sur demande aux médecins et pharmaciens.

129908

mars 2001

DIALYSIS SOLUTIONS INC., 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H2 Tel: (905) 884-6296

CSP #530 has sought and received approval from the FDA to use PrismaSate™ or Normocarb™ both as a dialysate and a replacement fluid for patients in CSP #530 treated with continuous renal replacement therapy. This non-labeled indication was approved for use under Investigational New Drug (IND) Application Number 67,631 with the Food and Drug Administration (FDA). The IND went into effect July 26, 2003. The VA Cooperative Studies Program is the sponsor for the IND. For additional information on the IND, see section I entitled “Introduction and Purpose”.

A summary of available published literature in human subjects outlining the use of both PrismaSate™ and Normocarb™ as a dialysate and a replacement fluid is provided in this document. This data is not intended to suggest that these solutions have been proven to be safe and effective when used as replacement fluids. This data was submitted to the FDA and was used to support that these solutions when used as replacement fluids will not cause harm to subjects enrolled in CSP #530.

### **Brief Summary of Previous Human Experience:**

All references indicate the use of a bicarbonate-buffered solution is safe. Some references indicate the additional safety benefit that occurs through using a commercially available bicarbonate based solution. This additional benefit is the result of reduced compounding errors and increased sterility.

One commercially available bicarbonate-buffered product is PrismaSate™ by Gambro Renal Products, Inc. PrismaSate™ is marketed as a device within the United States as a dialysate solution. In Europe, the sterile pyrogen free solution is also approved for use as a replacement fluid in patients with acute renal failure.

A second commercially available product, Normocarb™ by Dialysis Solutions, Inc., is also marketed as a device in the United States. The solution is approved in Canada as a drug through a DIN application. Information provided by the company shows this solution to be sterile, pyrogen free and manufactured in a facility that meets all cGMP requirements.

Optimal concentrations for replacement fluids used in continuous venovenous hemodiafiltration (CVVHDF) have been established through clinical trials. The optimal concentration for bicarbonate replacement is 35-40 mEq/L. Bicarbonate solution may be used in combination safely with either heparin sodium or trisodium citrate. Monitoring of sodium concentration based upon the load given is essential.

Bicarbonate-based replacement/dialysate solutions have been shown in clinical trials and retrospective analysis to be safe and effective for patients that have lactic acidosis or hepatic disease. Lactate based solutions cannot be used in these patient populations. In addition, the lactate load delivered during high volume (>2-3 liters/hour) CVVH or CVVHDF when lactate-buffered dialysate/replacement fluids are employed may exceed

the normal metabolic capacity of the liver. For this reason lactate-buffered fluids are contraindicated and bicarbonate-buffered fluids have been demonstrated to be safe. Fluid and electrolyte disturbances may develop during the performance of continuous renal replacement therapies. The risk of excessive volume removal or inadvertent volume administration has largely been eliminated through the use of modern equipment with ultrafiltration control. Electrolyte disturbances can result from errors in the compounding of dialysate and replacement fluids. This can be prevented through the use of commercially prepared fluids with strict quality control. Careful patient monitoring protocols remain essential to eliminating treatment-related adverse events for patients being treated with continuous renal replacement therapy.

## Literature Review

A brief overview of the published human experience with bicarbonate-buffered dialysis solutions from the literature is summarized below.

Zimmerman et al. studied and compared acid-base balance, lactate concentration and hemodynamic parameters during continuous venovenous hemodialysis (CVVHD) using bicarbonate or a lactate-buffered dialysate.<sup>4</sup> The study used a prospective randomized 48-hour crossover design in 26 critically ill patients. The use of bicarbonate dialysis solution (Normocarb<sup>TM</sup>) compared to acetate dialysis solution (Dianeal<sup>TM</sup>) for CVVHD provided equivalent acid-base control. Serum lactate levels were higher during dialysis while using lactate buffered solution with even a greater tendency for elevations in patients with severe liver disease. The use of the bicarbonate dialysis solution was appropriate, safe and effective.

Bunchman et al. describes experiences with the use of bicarbonate-based calcium-free dialysis solution (Normocarb<sup>TM</sup>) in combination with citrate anticoagulation in pediatric hemofiltration.<sup>5</sup> Improved quality of care and less hemodynamic instability was observed during continuous venovenous hemofiltration (CVVH). Patients demonstrated improved pH and plasma bicarbonate levels and lower plasma lactate levels. Additionally, use of pre-manufactured solutions versus pharmacy prepared solutions assured sterility, saved preparation time for the solutions, reduced the risk of compounding errors and ensured compliance with the industry current Good Manufacturing Practices (cGMP).

Leblanc et al. studied fifty critically ill patients with acute renal failure (ARF), multiple organ failure, and in need of mechanical ventilation.<sup>6</sup> The patients received continuous renal replacement therapy (CRRT) utilizing a prepared bicarbonate buffered dialysate containing 37 +/-3 mEq/L of bicarbonate. The solution was filtered, but due to the possible presence of endotoxins it was not used as replacement fluid. Use of the bicarbonate dialysis solution was free of complications and maintained good metabolic control for the patients. An improvement in acid-balance was reported with its use. This study was conducted prior to the development and approval of commercially available bicarbonate solutions.

Williams et al. investigated the effects of dialysate bicarbonate concentrations on controlling the acid base balance and nutritional status of acute renal failure patients.<sup>7</sup> The trial utilized a single blind double crossover design with two consecutive six-month periods. The trial demonstrated that bicarbonate dialysate concentrations of 40 mmol/l are safe and well tolerated producing control of acidosis as compared with lower concentrations of 30 mmol/l.

Human experience with bicarbonate-buffered replacement fluids published in the medical literature is summarized below.

Kierforf et al. reviewed the published data on substitution fluids with an emphasis upon control of acidosis, lactate concentration, uremia, and hemodynamic/metabolic alterations.<sup>8</sup> The review of studies supports the safe and effective use of bicarbonate-buffered replacement solutions especially for patients with reduced lactate metabolism, lactic acidosis, severe liver failure or following liver transplantation. Lactate based replacement solutions have negative effects on hemodynamic and metabolic parameters, enhanced protein catabolism and a decrease seen in regeneration of adenosine 5' triphosphate (ATP). There is also evidence of an increase load of daily lactate, and by using bicarbonate-based solutions these negative effects may be avoided.

Barenbrock et al. conducted an open, randomized multi-center trial in 117 patients to investigate the effects of lactate-buffered and bicarbonate-buffered replacement fluid on cardiovascular outcome in patients requiring continuous venovenous hemofiltration (CVVH) with acute renal failure.<sup>9</sup> The replacement fluid used for the study was manufactured by Fresenius Medical Care in Germany and contained a bicarbonate concentration 35 mEq/L. Results determined that blood lactate levels were significantly lower and blood bicarbonate levels higher in patients treated with bicarbonate-buffered replacement fluid. The number of hypotensive crises and cardiovascular events was statistically lower in the group treated with bicarbonate-buffered solutions. Outcome results indicated that patients receiving bicarbonate-buffered replacement fluid demonstrated correction of acidosis. A multiple regression analysis showed cardiovascular events were dependent on the type of replacement fluid used and previous cardiovascular disease. The data suggested that the patients treated with bicarbonate-buffered replacement fluid sustained fewer complications and demonstrated improved normalization of acidosis.

Gonella et al., in a letter to the editor, described the use of a commercially available bicarbonate replacement fluid developed in Italy containing a final concentration of 32 mmol/L of bicarbonate.<sup>10</sup> The reinfusate bag contained a bicarbonate solution and an acid solution separated until use. Twelve patients received hemodiafiltration and the bicarbonate replacement fluid over a three-year period. The bicarbonate-electrolyte solution allowed for physiological correction of acidosis without precipitation. The authors recommended the use of the bicarbonate replacement fluid when a large volume of reinfusate was needed or when the use of lactate or acetate was not justified.

Published human experience with bicarbonate-buffered dialysis and replacement fluid from the medical literature is summarized below.

Movilli et al. studied acetate-free biofiltration (AFB), hemodiafiltration (HDF) and intermittent bicarbonate hemodialysis (BD) in twelve elderly patients receiving regular dialysis for at least five months.<sup>11</sup> The open label randomized sequence study prospectively followed patients for 6 months while on each procedure. The bicarbonate-based dialysis solution, blood flow rate and dialysate flow rate were the same for all methods. Bicarbonate containing infusions were used post-dilution for the HDF (27-30mEq/L at 66+/-ml/min) and AFB (145mEq/L at 2.81+/-0.12 L/hr) procedures. HDF and AFB demonstrated better dialysis efficiency and better hemo-dynamic tolerance as compared to BD with statistically significant fewer episodes of hypotension. Acetate-free biofiltration showed better control of acid-base balance. No biochemical differences were noted with slightly better control of acidosis during AFB. The bicarbonate dialysis and postdilution bicarbonate infusion resulted in no safety concerns during the study period.

Venkataraman et al. retrospectively reviewed dosing patterns of continuous renal replacement therapy (CRRT) in patients with acute renal failure (ARF) in a large academic medical center.<sup>12</sup> Patients were treated with CVVHD, CVVH or CVVHDF. Commercially available lactate buffered solutions were utilized. Patients exhibiting lactate intolerance and/or lactic acidosis were prescribed custom bicarbonate-buffered solutions and replacement fluids when required for the mode of therapy prescribed. No safety or efficacy concerns were noted from the use of the solutions.

McLean et al. conducted a non-randomized crossover cohort study in 54 patients with and without liver dysfunction.<sup>2</sup> The patients sequentially underwent continuous venovenous hemodiafiltration (CVVHD) utilizing lactate-buffered dialysate and lactate-free dialysate with separate bicarbonate replacement. Over the 24-hour study duration, lactate-free dialysate provided more rapid control of acidosis with less total administration of buffer. Mean arterial blood pressure fell during lactate-buffered dialysis with increased inotrope use and increased during lactate-free dialysis with decreased inotrope use.

Davenport authored an article that addressed the needs and requirements associated with continuous renal replacement therapy (CRRT).<sup>13</sup> The summary discussed the need to ensure the solution sterility was maintained and how this has become less of a factor with the recent commercial availability of bicarbonate based fluids. They noted that several studies have demonstrated that both bicarbonate and lactate based solutions result in better control of acid-based balance and improvement in cardiovascular tolerance as compared to acetate. Other authors have shown bicarbonate to be superior to lactate. It was further recommended that for high volume exchanges, or those patients with severe tissue acidosis or liver failure, bicarbonate based fluids should be selected.

Heering et al. conducted a prospective, cohort study in 132 critically ill patients to evaluate hemofiltration replacement fluids on acid-base and cardiovascular

hemodynamics in patients with acute renal failure (ARF).<sup>1</sup> Patients were treated with either lactate-based, acetate-based or bicarbonate-based buffer hemofiltration fluids while receiving dialysis using continuous venovenous hemofiltration (CVVH). Results reported were that bicarbonate and lactate based fluids were superior to acetate-based solutions for correction of acidosis and maintaining cardiovascular control of hemodynamics.

Hilton PJ et al. studied a group of 200 patients over 7 years with acute renal failure complicated by lactic acidosis or lactate intolerance.<sup>14</sup> The patients were treated with continuous hemofiltration using a locally prepared bicarbonate-based replacement fluid. The authors were able to obtain control of acidosis in all patients without inducing either extracellular volume expansion or hypernatremia. They concluded that the combination of acute renal failure and lactic acidosis, which cannot be safely treated using lactate-buffered fluids, can be safely managed with bicarbonate-buffered continuous hemofiltration.

Thomas et al. conducted a prospective, randomized trial involving 41 intensive care patients receiving dialysis to compare the effects of using a lactate containing (44mmol/L) versus a bicarbonate (40mmol/L) containing dialysis and replacement fluid.<sup>3</sup> Replacement fluid was used at a mean rate of 1.7l/hr. No difference in acidosis correction during the first 24 hours occurred with the use of the different fluids.

The literature summarizing human experience with bicarbonate-buffered replacement solutions indicates possible improvement of acid-base balance and cardiovascular parameters compared to other types of solutions. No safety risks for patients were identified in the literature so long as sterile solutions free of precipitate were maintained.

## References

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## **D. Drug Accountability**

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Accountability for the use of each bag of PrismaSate™ and/or Normocarb™ used in patients in CSP #530 is required as part of the study documentation, for maintenance of the IND, and to provide a rebate to the sites using these solutions.

Accountability is maintained through the use of a two-part “Investigational Drug” label and the Drug Accountability documentation form.

Steps for drug accountability:

1. The left side of the “Investigational Drug” label must be affixed to every bag of PrismaSate™ and/or Normocarb™ used for patients enrolled in CSP #530. For details on labeling see section II entitled “Drug Treatment and Handling Procedures”.
2. The right side of the “Investigational Drug” label must be affixed to the “DAILY Drug Accountability Documentation Form”. Complete the additional information required on the form. (see example)
3. One Drug Accountability Documentation Form should be used each day for each patient enrolled in the study.
4. The original Drug Accountability Documentation Forms will be kept at the study site with other study records.
5. For sites wishing to participate in the rebate program for PrismaSate™ and Normocarb™, copy of the Drug Accountability Documentation Forms should be sent to the CSPCRPCC at the address listed below.

Kathy Swanson, M.S., R.Ph.  
Clinical Research Pharmacist  
CSPCRPCC (151-I)  
2401 Centre Ave. SE  
Albuquerque, NM 87106-4180  
(505) 248-3203  
Fax (505) 248-3205

6. Rebates will be calculated based on information on the Drug Accountability documentation. Rebates are calculated by taking the difference in the site’s contracted price minus the study rebate price multiplied by the number of bags/bottles used in study patients. Rebates will be calculated on a quarterly basis using the annual calendar.

**CSP #530 “Intensive vs. Conventional Renal Support in Acute Renal Failure”**

**DAILY Drug Accountability Documentation Form**

- 1. Fill in formation below.**
- 2. Place right side of tear-off label in the numbered boxed below.**
- 3. Use multiple sheets if needed. One patient per sheet.**
- 4. Mail copy of form to CSPCRPCC quarterly.**

Date: \_\_\_\_\_ Patient ID: \_\_\_\_\_

Site Name/Number: \_\_\_\_\_

Study Drug: \_\_\_\_\_ Lot/Expiration Date: \_\_\_\_\_

1	5	9
2	6	10
3	7	11
4	8	12

## **E. Reporting Serious Adverse Events**

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Adverse events in CSP #530 are only monitored if related to dialysis and catheter insertion.

All serious adverse events (SAEs) considered by the principle investigator to be related to the intensive or conventional renal support will be reported within 72 hours of being made aware of the event. This will include serious adverse events related to the dialysis or replacement solutions.

The definition of serious adverse events in the protocol follows the definition outlined in the ICH Harmonized Tripartite Guidelines E2A for Clinical Safety Data Management. These include:

1. Results in death
2. Life-threatening
3. Results in Disability/incapacity
4. Prolongs existing hospitalization
5. Other serious event as defined by investigator

Both expected and unexpected SAEs are to be reported. An expected event is previously known to occur or has been previously reported in the literature. An event is expected in light of the study intervention (e.g. hemodialysis, CRRT). Expected is NOT what you think might happen as a result of the underlying disease state of the patient (e.g. underlying critical illness or acute renal failure). An unexpected event is one that is not consistent with the information known in the medical literature about the study intervention. These may be more serious than what has been previously reported or have a different specificity.

“Related” is defined as having a “reasonable causal relationship” and is meant to convey that the facts or evidence suggest a causal relationship cannot be ruled out.

In addition, all deaths, regardless of cause or relationship, will be reported as serious adverse events. The protocol requires that related serious adverse events be collected until death, discharge from the hospital or for 30 days after randomization, whichever comes first.

The safety of the dialysis and catheter insertion is being followed using a specific case report form, Form 15 – Catheter Insertion Form. The Catheter Insertion Form, will track short-term adverse events and serious adverse events associated with dialysis use and catheter insertion. See the operations manual for details.

Serious events will also be monitored on Form 16 - Serious Adverse Event case report form. The operations manual contains details on how to complete this form. All serious adverse events are faxed to the West Haven Coordinating Center within 72 hours of

becoming aware of the event. The West Haven Coordinating Center will send these on to the Chairman's Office and Clinical Research Pharmacist for immediate evaluation.

The Cooperative Studies Program Clinical Research Pharmacy, as the IND Sponsor, will maintain a database of serious events for evaluation, coding using the Medical Dictionary for Regulatory Affairs (MedDRA) and trending. Periodic summaries will be provided as part of the IND annual report, DSMB information, and to the Study Chairman and Executive Committee. Serious events that are related and unexpected will be reported to the Site Investigators to share with the local IRB, the FDA, and the VA Cooperative Studies Program Central Office.

## **XV. OBSERVATIONAL STUDY: INSTRUCTIONS & CASE REPORT FORMS**

### **A. Description of Observational Study**

The primary purpose of this data collection is to ensure that the VA/NIH Acute Renal Failure Trial Network (ATN) Study (CSP #530) is conducted with maximal protection of the safety of patients in each of the two treatment arms. The Office for Human Research Protections (OHRP) of the US Department of Health and Human Services has specified that in all clinical trials there is a need to “assess the risks and potential benefits of each of the interventions for each arm...relative to concurrent routine clinical practice outside of the research context”. Since there is not a well-established standard of care for the management of renal replacement therapy in acute renal failure, it appears to be necessary to collect robust data on these processes of care provided for patients who are not participating in the ATN Study. The data collected in this observational study will be reported to the study Data and Safety Monitoring Board (DSMB), to the West Haven CSPCC Human Rights Committee and to each participating institution’s IRB.

#### ***Patient Selection***

The target sample population for this observational data collection will be patients meeting all of the screening criteria for the ATN Study with the exception of informed consent for participation in the interventional trial. We anticipate that the most common reason for non-enrollment of otherwise qualified patients will be the inability to obtain consent from the appropriate surrogate decision-maker within the necessary time frame. All patients selected for data collection in this observational cohort will need meet each of the following five inclusion criteria for the study:

1. Acute renal failure clinically consistent with a diagnosis of acute tubular necrosis, defined as:
  - Clinical setting of ischemic or nephrotoxic injury

**And**

- oliguria (urine output < 20 mL/hour) for > 24 hours, **or** an increase in serum creatinine of > 2 mg/dL (> 1.5 mg/dL in females) over baseline over a period of ≤ 4 days.
- 2. Plan for renal replacement therapy by the clinical team.
- 3. Receiving care in critical care unit (e.g., MICU, SICU, CCU).
- 4. One non-renal organ failure (SOFA organ system score ≥ 2) or the presence of sepsis.
- 5. Age > 18 years.

Patients excluded from the study based on the following exclusion criteria will also be excluded from the observational cohort:

1. Pre-morbid serum creatinine > 2 mg/dL (> 1.5 mg/dL in females).
2. Acute renal failure clinically believed to be due to an etiology other than ATN.
3. More than 72 hours since the patient met the definition of ARF **and** had a BUN >100 mg/dL.
4. > 1 hemodialysis treatment or > 24 hours of CRRT prior to screening.
5. Prior kidney transplant.
6. Pregnancy.
7. Prisoner.
8. Weight > 128.5 kg.
9. Non-candidacy for acute renal replacement therapy.
10. Moribund state.
11. Patient not expected to survive 28-days because of an irreversible chronic medical condition.
12. Comfort-measures only status.
13. Participation in a concurrent interventional trial.
14. Physician refusal to participation in the interventional trial.

***Data Collection***

The following data will be collected on the patients in the observational cohort:

1. Demographic data including age, gender, race and etiology of ARF.
2. Whether or not the patient received renal replacement therapy within 14 days of screening.
3. If the patient received renal replacement therapy within 14 days of screening:
  - a. Which day post-screening renal replacement therapy was initiated,
  - b. The indications for renal replacement therapy (e.g., volume overload, hyperkalemia, acidosis, uremic symptoms),
  - c. The blood urea nitrogen (BUN) concentration on the day renal replacement therapy was initiated,
  - d. The SOFA Cardiovascular score at the time of initiation of renal replacement therapy,
  - e. The modality of renal replacement therapy provided on each day between day-1 and day-14 post screening.

This data will be collected using **Form 22 – Entry Form (Observational Study)**. In addition, data on each renal replacement therapy treatment provided in the 14 days post screening will be collected using **Form 23 – Renal Replacement Therapy – Each Treatment (Observational Study)**, to provide accurate data regarding the actual delivered treatments. Form 23 is a modification of Form 9, with prohibited identifiers, specifically patient initials and treatment date, removed.

### ***Frequency of Data Collection***

At a minimum, patient data will be collected on this observational cohort during the first and final years of study enrollment. Provisionally, we are proposing to collect data on the first 10 patients meeting the criteria for the observational cohort from each VA site, and the first 25 patients at each non-VA site. This data collection will be repeated at the start of year 3. Additional data collection will be at the discretion of the study Executive Committee and the study Data and Safety Monitoring Board (DSMB).

**CSP530A – Observational Study**

**B. Instructions for Form 22 – Entry Form**  
**Enter Hospital No., Patient ID, and Date Form Completed.**

**A. Demographic Information**

1. Enter the patient's age in years.
2. Check the box that indicates the patient's gender.
3. Check the one box that indicates the patient's racial/ethnic origin.
4. Check the one box that best indicates the ATN etiology.

**B. RRT within 14 days of Screening** – Check the 'yes' box if the patient received RRT within 14 days of screening; check the 'no' box otherwise.

1. If 'no' is checked, skip the remainder of this form, enter staff initials at bottom of second page, and send the form to WH CSPCC.
2. If 'yes' is checked, complete the remainder of this form, complete a form 23 for each day of RRT received by the patient, and send the complete set of forms for this patient to WH CSPCC together in the same package.

**C. Renal Replacement Therapy Data**

1. Indicate on which day-post-screening that RRT was started, where day '01' is day of screening.
2. Indication for RRT – check all the indications listed below that apply.
3. Enter the value of the BUN on the date on which RRT was initiated.
4. Enter the Cardiovascular SOFA Score at the time of initiation of RRT.

VA WEST HAVEN CSP530A  
ACUTE RENAL FAILURE TRIAL NETWORK (OBSERVATIONAL STUDY)  
FORM 22 - ENTRY FORM

Hospital No.

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Patient ID

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Date Form Completed (mm/dd/yy)

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## A. Demographic Information

1. Age 

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 years2. Gender:     male     female

## 3. Racial/Ethnic Origin:

- |                                                        |                                                         |
|--------------------------------------------------------|---------------------------------------------------------|
| <input type="checkbox"/> White, not of Hispanic Origin | <input type="checkbox"/> Pacific Islander               |
| <input type="checkbox"/> Black, not of Hispanic Origin | <input type="checkbox"/> American Indian/Alaskan Native |
| <input type="checkbox"/> Hispanic                      | <input type="checkbox"/> Other                          |
| <input type="checkbox"/> Asian                         |                                                         |

## 4. Etiology of Acute Tubular Necrosis (choose one):

- Ischemic
- Nephrotoxic
- Sepsis
- Multifactorial

B. Did patient receive Renal Replacement Therapy within 14 day of Screening?-----  Yes     No

1. If no, please skip to the end of this form, enter staff initials, and send form to WH CSPCC.

2. If yes, complete the remainder of the form and send form to WH CSPCC with the patient's RRT forms (Observational Study Forms 23).

## C. Renal Replacement Therapy (RRT) Data

1. Day post-screening that RRT was started (day 01=screening day).

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2. Indication for RRT (choose all that apply).

- Volume overload
- Persistent hyperkalemia
- Severe metabolic acidosis
- Azotemia

3. BUN on date RRT initiated: 

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 mg/dL

4. SOFA Cardiovascular Score at time of initiation of RRT:

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Page 2 of 2

**CSP530A – Observational Study,  
Instructions for Form 22 – Entry Form**

**Enter Hospital No., Patient ID, and Date Form Completed.**

5. For **each** of days 1 through 14 post-screening, check the first box on the line for that day if no RRT was provided. If RRT was provided on that day, indicate the modality(s) used on that day by checking one or more of the appropriate boxes that appear after the ‘No RRT’ box. Remember that day 1 is the day of screening. **Check at least one box for each of the 14 days.**
6. Complete a Form 23 for each treatment provided on each of the 14 days post-screening.

**NOTE: Be sure to mail this Form 22 and all of the Form 23’s for the patient to WH CSPCC together in one package at the end of the 14-day post-screening period**

Enter the initials of the staff member who completed this form.

VA WEST HAVEN CSP530A  
ACUTE RENAL FAILURE TRIAL NETWORK (OBSERVATIONAL STUDY)  
FORM 22 - ENTRY FORM

Hospital No.

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Patient ID

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Date Form Completed (mm/dd/yy)

	/		/	
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5. For days 1 through 14 post-screening, indicate whether RRT was provided and if provided, what modality was used. For each day when RRT was provided, check all modalities that apply. Day 1 is day of screening.

Day 1:     No RRT     IHD     SLED     CRRTDay 2:     No RRT     IHD     SLED     CRRTDay 3:     No RRT     IHD     SLED     CRRTDay 4:     No RRT     IHD     SLED     CRRTDay 5:     No RRT     IHD     SLED     CRRTDay 6:     No RRT     IHD     SLED     CRRTDay 7:     No RRT     IHD     SLED     CRRTDay 8:     No RRT     IHD     SLED     CRRTDay 9:     No RRT     IHD     SLED     CRRTDay 10:     No RRT     IHD     SLED     CRRTDay 11:     No RRT     IHD     SLED     CRRTDay 12:     No RRT     IHD     SLED     CRRTDay 13:     No RRT     IHD     SLED     CRRTDay 14:     No RRT     IHD     SLED     CRRT

6. Complete a Form 23 for each treatment provided on each of the 14 days post screening.

NOTE: Mail Form 22 and all Forms 23 for this patient to WH CSPCC together at the end of the 14 day post-screening period.

Staff Initials

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**CSP530A – Observational Study.**

**C. Instructions for Form 23 – Renal Replacement Therapy – Each Treatment**

**Enter Hospital Number, Patient ID, Treatment Day (01, 02, ..., 14), Treatment Number this Day (e.g., the first treatment on this day is 1, the second treatment on this day is 2, etc.), and Date Form Completed.**

**When to complete this form: This form should be completed for each treatment given on each of the up to 14 treatment days on which the patient received RRT. Note that ‘day 1’ refers to the day the patient was screened.**

**A. Time of day the Renal Replacement Therapy was started – enter the value as military time; e.g., 8am will be 0800, noon will be 1200, and 8pm will be 2000.**

**Note: If the patient is continuing on continuous therapy from the previous day, enter treatment start time for the ICU flow sheet for the day. If the data flow sheet used runs other than midnight to midnight, use the institution 24-hour cycle for each day of therapy.**

1. Check ‘yes’ or if patient is on continuous therapy, continued from the previous day; check ‘no’ otherwise.

**B. Indicate type of renal replacement therapy – check one box only and complete the appropriate section for that type of RRT, plus complete section F for all types of RRT.**

**C. Isolated Ultrafiltration**

1. Indication for isolated ultrafiltration.
  - a. Check ‘yes’ if there is severe edema; check ‘no’ otherwise. Severe is defined as edema with evidence of tissue compromise.
  - b. Check one box to indicate the clinical examination of the lungs.
  - c. Enter the CVP value in mmHg. Check the ‘N/A’ box if not available
  - d. Enter the pulmonary artery pressure as systolic/diastolic pressure in mmHg. Check the ‘N/A’ box if not available.
  - e. Enter the pulmonary capillary occlusion pressure (“wedge” pressure) value in mmHg. Check the ‘N/A’ box if not available.
  - f. For oxygenation, enter the hemoglobin oxygenation saturation (SaO<sub>2</sub>), measured transcutaneously, in percent saturation or the arterial oxygenation (PaO<sub>2</sub>), measured on an arterial blood gas in mmHg. Provide the administered oxygen as either the percent oxygen administered (FiO<sub>2</sub>) (e.g., 0.40=40%) or as the oxygen flow rate in liters/minute, as appropriate.
2. Enter the duration of ultrafiltration in hours and minutes. If there are no minutes, please enter 00 in the minutes boxes. If there are no hours, please enter 00 in the hours boxes.
3. Enter the dialyzer code (see the coding section of the Ops Manual).
4. Enter the blood flow rate in mL/minute.
5. Enter the pre-treatment weight in kilograms. Check the ‘N/A’ box if value not available.
6. Enter the amount of net fluid removed in liters.

ACUTE RENAL FAILURE TRIAL NETWORK (OBSERVATIONAL STUDY)  
FORM 23 - RENAL REPLACEMENT THERAPY - EACH TREATMENT

Hospital No.	Patient ID	Treatment Day Code 01,02,...,14	Treatment No. This Day	Date Form Completed (mm/dd/yy)
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>

A. Time of day RRT started (military)  hours

1. If on continuous therapy, is it continued from previous day? .....  Yes  No

B. Selection of RRT Modality

1. Cardiovascular SOFA Score

2. Type of RRT (check one)

Hemodialysis (complete section D)

CRRT (complete section E)

SLED (complete section D)

Isolated Ultrafiltration (complete section C)

C. ISOLATED ULTRAFILTRATION

1. Indication for isolated ultrafiltration

a. Severe Edema .....  Yes  No

b. Lungs (check one) .....  Clear  Pulmonary Vascular Congestion

c. CVP .....  mmHg  N/A\*

d. Pulmonary Artery Pressure (systolic/diastolic) .....  /  mmHg  N/A\*

e. Pulmonary Capillary Occlusion Pressure .....  mmHg  N/A\*

f. Oxygenation ..... SaO<sub>2</sub>  % OR PaO<sub>2</sub>  mmHg

FiO<sub>2</sub>  % OR Oxygen flow rate  liters/min

2. Duration of ultrafiltration .....  hours  minutes

3. Dialyzer (see Ops manual for codes) .....

4. Blood flow rate .....  mL/min

5. Pre-treatment weight .....  .  kg  N/A\*

6. Fluid removal .....  .  L

**Enter Hospital Number, Patient ID, Treatment Day (01, 02, ... , 14), Treatment Number this Day, and Date Form Completed.**

**D. Hemodialysis or SLED**

1. Dialyzer code (see coding section of Ops Manual).
2. Enter the actual duration of dialysis in hours and minutes. If there are no minutes, please enter 00 for minutes. If there are no hours please enter 00 for hours.
3. Enter the average achieved blood flow rate in mL/minute.
4. Enter the dialysate flow rate in mL/minute.
5. Enter the pre-treatment weight in kilograms.
6. Enter the **net** amount of fluid removed in liters.
7. If assessment of dialysis adequacy was performed, mark 'yes'; otherwise mark 'no'.

**If yes,**

- a. Enter the BUN value at the initiation of today's treatment as mg/dL.
  - b. Enter the BUN value at the termination of today's treatment as mg/dL.
  - c. Enter the value of spKt/V as per worksheet VIII-5.
8. Anticoagulation – Check the one box that indicates the anticoagulant. If 'other' is checked, please specify the agent used in the box provided.
  9. Check 'yes' if clotting of extracorporeal circuit dialyzer required replacement of the hemodialyzer; check 'no' otherwise.
  10. a. Enter the blood pressure taken at the initiation of the treatment (Pre-dialysis BP) in mmHg.  
b. Enter the lowest blood pressure documented during treatment in mmHg.

**E. CRRT**

1. Enter the code for the hemodiafilter (see the coding section of the Ops Manual).
2. Enter the duration of the therapy in hours and minutes. If there are no minutes, enter 00 for minutes. If there are no hours, enter 00 for hours.
3. Enter prescribed blood flow rate in mL/minute.
4. Dialysate flow rate:
  - a. Enter the prescribed dialysate flow rate as mL/hour.
  - b. Enter the code for the dialysate used (see the coding section of the Ops Manual).
5. Replacement fluid administration rate:
  - a. Enter the prescribed replacement fluid administration rate as mL/hour.
  - b. Enter the code for the replacement fluid used (see the coding section of the Ops Manual).

ACUTE RENAL FAILURE TRIAL NETWORK (OBSERVATIONAL STUDY)  
FORM 23 - RENAL REPLACEMENT THERAPY - EACH TREATMENT

Hospital No.	Patient ID	Treatment Day Code 01,02,...,14	Treatment No. This Day	Date Form Completed (mm/dd/yy)
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>

D. HEMODIALYSIS or SLED

1. Dialyzer (see Ops Manual for codes) -----

2. Actual duration of dialysis (hours and minutes) -----  hours  mins

3. Blood flow rate (average achieved) -----  mL/min

4. Dialysate flow rate -----  mL/min

5. Pre-dialysis weight -----  .  kg  N/A\*

6. Net fluid removal (based on ultrafiltration monitor and administered fluids) -----  .  L

7. Assessment of dialysis adequacy performed? ----- Yes  No

If yes, a. BUN at initiation of today's treatment -----  mg/dL

b. BUN at termination of today's treatment -----  mg/dL

c. Calculated spKt/V -----  .

8. Anticoagulation (choose one)

None  Heparin  Citrate  Other, specify

9. Clotting of extracorporeal circuit requiring hemodialyzer replacement? -----  Yes  No

10. a. Blood pressure at initiation of treatment -----  /  mmHg

b. Lowest documented blood pressure during treatment -----  /  mmHg

E. CRRT

1. Hemodiafilter (see Ops Manual for codes) -----

2. Actual duration of therapy (hours and minutes) -----  hours  mins

3. Blood flow rate (prescribed) -----  mL/min

4. Dialysate flow rate (prescribed) ----- a.  mL/hour

b. Dialysate code  (see Ops Manual)

5. Replacement fluid administration rate (prescribed) a.  mL/hour

b. Replacement Fluid Code  (see Ops Manual)

**Enter Hospital Number, Patient ID, the Treatment Day (01, 02, ... , 14), Treatment Number this Day, and Date Form Completed.**

**E. CRRT (cont'd)**

6. Enter the prescribed ultrafiltration rate as mL/hour.
7. Enter the actual 24-hour effluent volume in liters.
8. Anticoagulation – Check the one box that indicates the anticoagulant.  
If 'other' is checked, please specify the agent used in the box provided.
9. Check 'yes' if clotting of the extracorporeal circuit during dialysis required replacement of the hemodiafilter; check 'no' otherwise.
10. Enter the number of hemodiafilters used during this 24-hour treatment period.

**F. Complications of Therapy – For each of the complications listed below that occurred during this RRT session, please mark either the 'no' or the 'yes' box.**

1. Anaphylactic reaction to dialyzer ("first-use" reaction).
2. Hypotension requiring initiation of pressor support during treatment.
3. Hypotension requiring discontinuation of therapy.
4. Hypotension requiring other intervention.
5. Air embolism.
6. Bleeding (e.g., due to system disconnection or dialyzer rupture).
7. New onset of serious arrhythmia requiring discontinuation of therapy (e.g., rapid supraventricular tachycardia with hypotension, ventricular tachycardia)
8. Iatrogenic fluid and/or electrolyte imbalances
  - a. If yes, enter the code for the type of imbalance (see coding section of the Ops Manual).
9. Seizures
10. Other – If 'yes' is marked, please specify what the complication is in the boxes provided.

Enter the initials of the staff member completing the form.

ACUTE RENAL FAILURE TRIAL NETWORK (OBSERVATIONAL STUDY)  
FORM 23 - RENAL REPLACEMENT THERAPY - EACH TREATMENT

Hospital No.	Patient ID	Treatment Day Code 01,02,...,14	Treatment No. This Day	Date Form Completed (mm/dd/yy)
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>

E. CRRT (cont'd)

6. Ultrafiltration rate (prescribed) -----  mL/hour

7. 24-hour effluent volume (actual) -----  .  L

8. Anticoagulation (choose one)

None    Heparin    Citrate    Other, specify

9. Clotting of extracorporeal circuit requiring hemodiafilter replacement? -----  Yes    No

10. Number of hemodiafilters used during this 24-hour treatment period -----

F. COMPLICATIONS OF THERAPY (complete for all types of RRT)

	No	Yes
1. Anaphylactic reaction to dialyzer ("first-use" reaction) -----	<input type="checkbox"/>	<input type="checkbox"/>
2. Hypotension requiring initiation of pressor support during treatment -----	<input type="checkbox"/>	<input type="checkbox"/>
3. Hypotension requiring discontinuation of therapy -----	<input type="checkbox"/>	<input type="checkbox"/>
4. Hypotension requiring other intervention -----	<input type="checkbox"/>	<input type="checkbox"/>
5. Air embolism -----	<input type="checkbox"/>	<input type="checkbox"/>
6. Bleeding (e.g., due to system disconnection or dialyzer rupture) -----	<input type="checkbox"/>	<input type="checkbox"/>
7. New onset of serious arrhythmia requiring discontinuation of therapy (e.g., rapid supraventricular tachycardia with hypotension, ventricular tachycardia) -----	<input type="checkbox"/>	<input type="checkbox"/>
8. Iatrogenic fluid and/or electrolyte imbalances -----	<input type="checkbox"/>	<input type="checkbox"/>
a. If yes, type of imbalance (see OPs Manual) <input type="text"/> <input type="text"/>		
9. Seizures -----	<input type="checkbox"/>	<input type="checkbox"/>
10. Other -----	<input type="checkbox"/>	<input type="checkbox"/>

Specify:

--

Staff Initials

<input type="text"/> <input type="text"/> <input type="text"/>
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**XVI. CODING APPENDICES**

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## A. Drug Codes

Drugs listed on Form 8 are cross-referenced by trade and generic name for your convenience. The diuretics, non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 inhibitors, ACE inhibitors, and angiotensin receptor blockers are on this list and are in separate lists below.

**All drugs on form 8** - Beside each drug name, in the right column, is the notation for which drug to check on Form 8.

Drug name by trade or generic	Check this on Form 8
Ablecet <sup>R</sup>	Amphotericin B
Accupril <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
Aceon <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
acetazolamide	Diuretics
acetylcysteine	Acetylcysteine
activated drotrecogin alpha	Activated drotrecogin alpha
activated Protein C	Activated drotrecogin alpha
Advil <sup>R</sup>	NSAIDs/Cox-2 inhibitors
Aldactone <sup>R</sup>	Aldosterone antagonists
Altace <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
Aleve <sup>R</sup>	NSAIDs/Cox-2 inhibitors
AmBisome <sup>R</sup>	Amphotericin B
amikacin	Aminoglycoside antibiotics
amikacin sulfate	Aminoglycoside antibiotics
Amikin <sup>R</sup>	Aminoglycoside antibiotics
Amphocin <sup>R</sup>	Amphotericin B
Amphotec <sup>R</sup>	Amphotericin B
amphotericin B	Amphotericin B
Ansaid <sup>R</sup>	NSAIDs/Cox-2 inhibitors
Aranesp <sup>R</sup>	Erythropoietic agents
Atacand <sup>R</sup>	Angiotensin receptor blockers (ARB)
Avapro <sup>R</sup>	Angiotensin receptor blockers (ARB)
benazepril	Angiotensin converting enzyme inhibitors (ACEI)
Benicar <sup>R</sup>	Angiotensin receptor blockers (ARB)
Bextra <sup>R</sup>	NSAIDs/Cox-2 inhibitors
bumetanide	Diuretics
Bumex <sup>R</sup>	Diuretics
candesartan	Angiotensin receptor blockers (ARB)
Capoten <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
captopril	Angiotensin converting enzyme inhibitors (ACEI)

Celebrex <sup>R</sup>	NSAIDs/Cox-2 inhibitors
celecoxib	NSAIDs/Cox-2 inhibitors
Clinoril <sup>R</sup>	NSAIDs/Cox-2 inhibitors
contrast media (not gadolinium)	X-ray contrast media (not gadolinium)
Corlopan <sup>R</sup>	Fenoldopam
Cozaar <sup>R</sup>	Angiotensin receptor blockers (ARB)
cyclosporin	Cyclosporin
cyclosporin A	Cyclosporin
darbepoetin alfa	Erythropoietic agents
Daypro <sup>R</sup>	NSAIDs/Cox-2 inhibitors
Demadex <sup>R</sup>	Diuretics
Diamox <sup>R</sup>	Diuretics
diclofenac	NSAIDs/Cox-2 inhibitors
Diovan <sup>R</sup>	Angiotensin receptor blockers (ARB)
drotrecogin alpha	Activated drotrecogin alpha
enalapril	Angiotensin converting enzyme inhibitors (ACEI)
enalaprilat	Angiotensin converting enzyme inhibitors (ACEI)
eplerenone	Aldosterone antagonists
EPO	Erythropoietic agents
epoetin alfa	Erythropoietic agents
Epogen <sup>R</sup>	Erythropoietic agents
eprosartan	Angiotensin receptor blockers (ARB)
erythropoietin	Erythropoietic agents
etodolac	NSAIDs/Cox-2 inhibitors
Feldene <sup>R</sup>	NSAIDs/Cox-2 inhibitors
fenoldopam	Fenoldopam
fenoprofen	NSAIDs/Cox-2 inhibitors
flurbiprofen	NSAIDs/Cox-2 inhibitors
fosinopril	Angiotensin converting enzyme inhibitors (ACEI)
Fungizone <sup>R</sup>	Amphotericin B
furosemide	Diuretics
Garamycin <sup>R</sup>	Aminoglycoside antibiotics
gentamicin	Aminoglycoside antibiotics
gentamycin sulfate	Aminoglycoside antibiotics
hydrochlorothiazide	Diuretics
HydroDIURIL <sup>R</sup>	Diuretics
ibuprofen	NSAIDs/Cox-2 inhibitors
Indocin <sup>R</sup>	NSAIDs/Cox-2 inhibitors
indomethacin	NSAIDs/Cox-2 inhibitors
Inspra <sup>R</sup>	Aldosterone antagonists
irbesartan	Angiotensin receptor blockers (ARB)
kanamycin	Aminoglycoside antibiotics
kanamycin sulfate	Aminoglycoside antibiotics
Kantrex <sup>R</sup>	Aminoglycoside antibiotics

ketoprofen	NSAIDs/Cox-2 inhibitors
ketorolac	NSAIDs/Cox-2 inhibitors
Lasix <sup>R</sup>	Diuretics
lisinopril	Angiotensin converting enzyme inhibitors (ACEI)
Lodine <sup>R</sup>	NSAIDs/Cox-2 inhibitors
losartan	Angiotensin receptor blockers (ARB)
Lotensin <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
Mavik <sup>R</sup>	Anti-tensin converting enzyme inhibitors (ACEI)
meclofenamate	NSAIDs/Cox-2 inhibitors
meloxicam	NSAIDs/Cox-2 inhibitors
metolazone	Diuretics
Micardis <sup>R</sup>	Angiotensin receptor blockers (ARB)
Mobic <sup>R</sup>	NSAIDs/Cox-2 inhibitors
moexipril	Angiotensin converting enzyme inhibitors (ACEI)
Monopril <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
Motrin <sup>R</sup>	NSAIDs/Cox-2 inhibitors
Mucomyst <sup>R</sup>	Acetylcysteine
Mucosil <sup>R</sup>	Acetylcysteine
n-acetylcysteine	Acetylcysteine
nalbumezone	NSAIDs/Cox-2 inhibitors
Nalfon <sup>R</sup>	NSAIDs/Cox-2 inhibitors
Naprosyn <sup>R</sup>	NSAIDs/Cox-2 inhibitors
naproxen	NSAIDs/Cox-2 inhibitors
Nebcin <sup>R</sup>	Aminoglycoside antibiotics
Neoral <sup>R</sup>	Cyclosporin
olmesartan	Angiotensin receptor blockers (ARB)
Orudis <sup>R</sup>	NSAIDs/Cox-2 inhibitors
oxaprozin	NSAIDs/Cox-2 inhibitors
perindopril	Angiotensin converting enzyme inhibitors (ACEI)
piroxicam	NSAIDs/Cox-2 inhibitors
Prinivil <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
Procrit <sup>R</sup>	Erythropoietic agents
Prograf <sup>R</sup>	Tacrolimus
quinapril	Angiotensin converting enzyme inhibitors (ACEI)
ramipril	Angiotensin converting enzyme inhibitors (ACEI)
Relafen <sup>R</sup>	NSAIDs/Cox-2 inhibitors
rofecoxib	NSAIDs/Cox-2 inhibitors
Sandimmune <sup>R</sup>	Cyclosporin

spironolactone	Aldosterone antagonists
sulindac	NSAIDs/Cox-2 inhibitors
tacrolimus	Tacrolimus
telmisartan	Angiotensin receptor blockers (ARB)
Teveten <sup>R</sup>	Angiotensin receptor blockers (ARB)
thiazides	Diuretics
tobramycin	Aminoglycoside antibiotics
Tolectin <sup>R</sup>	NSAIDs/Cox-2 inhibitors
tolmetin	NSAIDs/Cox-2 inhibitors
Toradol <sup>R</sup>	NSAIDs/Cox-2 inhibitors
torseamide	Diuretics
trandolapril	Angiotensin converting enzyme inhibitors (ACEI)
Univasc <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
valdecoxib	NSAIDs/Cox-2 inhibitors
valsartan	Angiotensin receptor blockers (ARB)
Vasotec <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
Vasotec I.V. <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)
Vioxx <sup>R</sup>	NSAIDs/Cox-2 inhibitors
Voltaren <sup>R</sup>	NSAIDs/Cox-2 inhibitors
Xigris <sup>R</sup>	Activated drotrecogin alpha
x-ray contrast media (not gadolinium)	X-ray contrast media (not gadolinium)
Zaroxolyn <sup>R</sup>	Diuretics
Zestril <sup>R</sup>	Angiotensin converting enzyme inhibitors (ACEI)

**Diuretics** – Check this on Form 8 for any drugs named in the table below.

Drug name by trade or generic
acetazolamide
bumetanide
Bumex <sup>R</sup>
Demadex <sup>R</sup>
Diamox <sup>R</sup>
furosemide
hydrochlorothiazide
HydroDIURIL <sup>R</sup>
Lasix <sup>R</sup>
metolazone
thiazides
toremide
Zaroxolyn <sup>R</sup>

**Non-steroidal anti-inflammatory (NSAIDs) and COX-2 inhibitors** - Check this on form 8 for any drugs named in the table below.

Drug name by trade or generic
Advil <sup>R</sup>
Aleve <sup>R</sup>
Ansaid <sup>R</sup>
Bextra <sup>R</sup>
Celebrex <sup>R</sup>
celecoxib
Clinoril <sup>R</sup>
Daypro <sup>R</sup>
diclofenac
etodolac
Feldene <sup>R</sup>
fenoprofen
flurbiprofen
ibuprofen
Indocin <sup>R</sup>
indomethacin
ketoprofen
ketorolac
Lodine <sup>R</sup>
meclofenamate
meloxicam
Mobic <sup>R</sup>
Motrin <sup>R</sup>

nalbumentone
Nalfon <sup>R</sup>
Naprosyn <sup>R</sup>
naproxen
Orudis <sup>R</sup>
oxaprozin
piroxicam
Relafen <sup>R</sup>
rofecoxib
sulindac
Tolectin <sup>R</sup>
tolmetin
Toradol <sup>R</sup>
valdecoxib
Vioxx <sup>R</sup>
Voltaren <sup>R</sup>

**ACE inhibitors** – check this on form 8 for any of the drugs named in the table below.

Drug name by trade or generic
Accupril <sup>R</sup>
Aceon <sup>R</sup>
Altace <sup>R</sup>
benazepril
Capoten <sup>R</sup>
captopril
enalapril
enalaprilat
fosinopril
lisinopril
Lotensin <sup>R</sup>
Mavik <sup>R</sup>
moexipril
Monopril <sup>R</sup>
Perindopril
Prinivil <sup>R</sup>
quinapril
ramipril
trandolapril
Univasc <sup>R</sup>
Vasotec <sup>R</sup>
Vasotec I.V. <sup>R</sup>
Zestril <sup>R</sup>

**Angiotensin receptor blockers** – check this on form 8 for any of the drugs named below.

Drug name by trade or generic
Atacand <sup>R</sup>
Avapro <sup>R</sup>
Benicar <sup>R</sup>
candesartan
Cozaar <sup>R</sup>
Diovan <sup>R</sup>
eprosartan
irbesartan
losartan
Micardis <sup>R</sup>
olmesartan
telmisartan
valsartan

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**B. Serious Adverse Event Codes for FORM 16**

<b>Serious Adverse Event Code</b>	<b>Description of Event</b>
<b>COMPLICATIONS WITH DIALYSIS TREATMENT</b>	
001	Anaphylactic reaction to dialyzer (“first-use” reaction)
002	Hypotension requiring discontinuation of dialysis
003	Hypotension that is life-threatening but does not result in discontinuation of dialysis
005	Bleeding (e.g., due to system disconnection or dialyzer rupture)
006	New onset of serious arrhythmia requiring discontinuation of dialysis (i.e. rapid supraventricular tachycardia with hypotension, ventricular tachycardia)
007	Iatrogenic fluid imbalances
008	Iatrogenic electrolyte imbalances
009	Seizures
010	Stroke
011	Hypotension requiring initiation of pressor support during treatment

<b>COMPLICATIONS WITH DIALYSIS CATHETER</b>	
100	Catheter malfunction
101	Vascular injury requiring surgical intervention
102	Pneumothorax
103	Hemothorax
104	Catheter related infection
105	Protracted bleeding at catheter insertion site
106	Inadvertent arterial puncture
107	Local venous thrombosis
108	Venous thromboembolism
109	Air embolism
110	Catheter associated bacteremia
111	Serious cardiac arrhythmia
<b>OTHER COMPLICATIONS</b>	
999	Other serious complications

**C. Etiologies of ARF Other Than ATN**

**CODE Etiology of ARF**

- 01 Pre-renal azotemia
- 02 Obstructive uropathy
- 03 Allergic interstitial nephritis
- 04 Acute or rapidly progressive glomerulonephritis
- 05 Vasculitis
- 06 Hemolytic-uremic syndrome (HUS)/  
Thrombotic thrombocytopenic purpura (TTP)
- 07 Malignant hypertension
- 08 Scleroderma renal crisis
- 09 Atheroembolism
- 10 Multiple myeloma
- 11 Functional or surgical nephrectomy (bilateral)
- 12 Hepatorenal syndrome
- 13 Cyclosporin or tacrolimus nephrotoxicity
- 14 Tumor lysis syndrome
- 99 Other

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**D. Electrolyte Disturbance/Imbalance Codes**

**Code**

- 01 Hyponatremia
- 02 Hypernatremia
- 03 Hypokalemia
- 04 Hyperkalemia
- 05 Hypocalcemia
- 06 Hypercalcemia
- 07 Hypomagnesemia
- 08 Hypermagnesemia
- 09 Metabolic Acidosis
- 10 Metabolic Alkalosis
- 11 Hypophosphatemia
- 88 Other

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**E. CVVHDF Fluids**

**Code**

- 01 Primasate
- 02 Normocarb
- 03 Custom prepared
- 04 Other

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## **F. Microbiology Codes**

### **Code**

- 00 Organism 1 - negative culture
- 01 Staphylococcus aureus – methicillin sensitive (MSSA)
- 02 Staphylococcus aureus – methicillin resistant (MRSA)
- 03 Staphylococcus epidermidis
- 04 Streptococcus pneumoniae
- 05 Viridans Streptococcus species
- 06 Enterococcus faecalis – Vancomycin sensitive
- 07 Enterococcus faecalis – Vancomycin resistant (VREF)
- 08 Enterococcus faecium
- 09 Other Gram Positive Organisms
- 10 Escherichia coli
- 11 Klebsiella species
- 12 Pseudomonas aeruginosa
- 13 Pseudomonas species (non aeruginosa)
- 14 Enterobacter species
- 15 Serratia species
- 16 Proteus species
- 17 Other Gram Negative Organisms
- 18 Candida species
- 19 Other fungal species

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## G. Hemodialyzers

		Urea Clearance			
Blood Flow (mL/min)		200	300	400	500
Hemodialyzer					
Code	Name				
01	Baxter PSN 120	180	228	258	279
02	Baxter PSN 140	184	237	270	293
03	Baxter PSN 170	189	250	289	316
04	Baxter PSN 210	194	263	308	340
05	Baxter CT 110G	192	261	301	
06	Baxter CT 190G	197	273	323	
07	Baxter Exceltra 150	193	262	305	332
08	Baxter Exceltra 170	196	260	310	341
09	Baxter Exceltra 190	197	273	323	354
10	Baxter Exceltra Plus 210	199	287	350	384
11	Fresenius F-6	180	222	244	
12	Fresenius F-7NR	184	236	265	
13	Fresenius F-8	186	240	275	
14	Fresenius F-60A	185	240	280	
15	Fresenius F-60B	185	240	280	
16	Fresenius F-70NR	187	245	275	
17	Fresenius F-80A	190	246	292	
18	Fresenius F-80B	190	246	292	
19	Fresenius F-80M	190	246	292	
20	Fresenius Optiflux 160NR	194	266	308	
21	Fresenius Optiflux 180NR	196	274	323	
22	Fresenius Optiflux 200NR	197	277	330	
23	Gambro GFS Plus 20	192	242	271	
24	Gambro Polyflux 14S	186	242	278	
25	Gambro Polyflux 17R	191	254	295	
26	Gambro Polyflux 17S	191	254	295	
27	Gambro Polyflux 21R	195	267	315	346
28	Gambro Polyflux 21S	195	267	315	346
29	Gambro Polyflux 24R		274	326	360
30	Gambro Polyflux 24S		287	355	405
31	Hospal Filtral 20		250		
32	Terumo EE 220	196	261	311	
33	Toray B3-1.6A	188	238	275	296
34	Toray B3-2.0A	193	255	298	324
35	Toray BK-1.6U	187	245	280	302

		Urea Clearance			
Blood Flow (mL/min)		200	300	400	500
Hemodialyzer					
Code	Name				
36	Toray BK-2.1U	194	263	306	334
37	Toray BS-1.3	193	255	296	
38	Toray BS-1.6	195	266	312	
39	Toray BS-1.8	198	273	325	
40	Gambro Polyflux 140H	193	262	309	
41	Gambro Polyflux 170H	196	270	321	
42	Gambro Polyflux 210H	281	339	378	
43	Gambro Polyflux 6L	186	242	281	
44	Gambro Polyflux 8L	190	253	296	325
45	Gambro Polyflux 10L		263	311	342
99	Other				

## **H. Hemofilters**

### **Code**

01	Asahi PAN-03
02	Asahi PAN-06
03	Asahi PAN-10
04	Baxter CT190
05	Fresenius AV600
06	Fresenius F4
07	Fresenius F40
08	Fresenius F70NR
09	Fresenius Optiflux 200NR
10	Gambro Multiflow 60 (M60)
11	Gambro Multiflow 100 (M100)
12	Gambro HF1000
13	Fresenius Optiflux 160NR
14	Accura F160NR
99	Other

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## I. Tube Feeding/Oral Nutrition Codes

### Code

01	Additions	(Nestle)
02	Advera (Fat malabsorbtion)	(Ross)
03	Alitraq	(Ross)
04	AltraQ	(Ross)
05	BOOST	(Mead Johnson)
06	BOOST Breeze	(Mead Johnson)
07	BOOST Hi Pro Powder	(Mead Johnson)
08	BOOST High Protein	(Mead Johnson)
09	BOOST High Protein Powder	(Mead Johnson)
10	BOOST Plus	(Mead Johnson)
11	BOOST w/Fiber	(Mead Johnson)
12	Carnation Instant Breakfast	(Nestle)
13	Casec (Protein)	(Mead Johnson)
14	Choice DM Beverage	(Mead Johnson)
15	Choice DM TF	(Mead Johnson)
16	Compleat	(Novartis)
17	Compleat Pediatric	(Novartis)
18	Comply	(Mead Johnson)
19	Criticare HN	(Mead Johnson)
20	Crucial	(Nestle)
21	Deliver 2.0	(Mead Johnson)
22	DiabetaSource	(Novartis)
23	DiabetaSource AC	(Novartis)
24	Diabetisource AC	(Novartis)
25	Enlive!	(Ross)
26	Ensure	(Ross)
27	Ensure Fiber w/FOS	(Ross)
28	Ensure High Calcium	(Ross)
29	Ensure High Protein	(Ross)
30	Ensure Light	(Ross)
31	Ensure Plus	(Ross)
32	Ensure Plus HN	(Ross)
33	Ensure Plus HN	(Ross)
34	Ensure Powder	(Ross)
35	Ensure Powder	(Ross)
36	Epular (Milk Protein, Soybean Oil)	(VistaPharm)
37	Equalyte	(Ross)
38	f.a.a.	(Nestle)
39	FiberBasics	(Hormel)
40	Fibersource HN	(Novartis)
41	Fibersource Standard	(Novartis)
42	Forta Drink	(Ross)
43	Forta Shake Powder	(Ross)

## Tube Feeding/Oral Nutrition Codes (continued)

44	Glucerna	(Ross)
45	Glucerna Shake	(Ross)
46	Glutasorb	(Hormel)
47	Glutsorb	(Hormel)
48	Glytrol	(Nestle)
49	Great Shakes	(Hormel)
50	Hormel Instant Soluble Fiber (Fiber)	(Hormel)
51	HyFiber (Fiber)	(National Nutrition)
52	Immun-Aid	(McGaw)
53	Impact	(Novartis)
54	Impact 1.5	(Novartis)
55	Impact Glutamine	(Novartis)
56	Impact Recover	(Novartis)
57	Impact w/Fiber	(Novartis)
58	IntensiCal	(Mead Johnson)
59	Introlite	(Ross)
60	Isocal	(Mead Johnson)
61	Isocal HN	(Mead Johnson)
62	Isocal HN Plus	(Mead Johnson)
63	Isosource 1.5	(Novartis)
64	Isosource HN	(Novartis)
65	Isosource Standard	(Novartis)
66	Isosource VHN	(Novartis)
67	Jevity	(Ross)
68	Jevity Plus	(Ross)
69	Kemps Plus	(Hormel )
70	L- Argiment (L-Glu and L-Arg)	(National Nutrition)
71	Lipasorb (Whole Protein/High MCT)	(Mead Johnson)
72	Magnacal Renal	(Mead Johnson)
73	MCT Oil (MCT)	(Mead Johnson)
74	Med Pass 2.0	(Hormel)
75	Meritene (Protein)	(Novartis)
76	Microlipid (50% Safflower Oil)	(Mead Johnson)
77	Mighty Shakes	(Hormel)
78	Mighty Shakes No Sugar Added	(Hormel)
79	Moducal Powder (Maltodextrin)	(Mead Johnson)
80	Modulen IBD	(Nestle)
81	Nepro	(Ross)
82	Nestle VHC 2.23	(Nestle)
83	Novasource Pulmonary	(Novartis)
84	Novasource Renal	(Novartis)
85	NuBasics	(Nestle)
86	NuBasics Juice Drink	(Nestle)
87	NuBasics Plus	(Nestle)

## Tube Feeding/Oral Nutrition Codes (continued)

88	NuBasics VHP	(Nestle)
89	Nutrament	(Mead Johnson)
90	NutraShake Egg/Pro	(Ross)
91	NutraShake HiCal	(Ross)
92	NutraShake Juice/Fiber	(Ross)
93	Nutren 1.0	(Nestle)
94	Nutren 1.0 w/Fiber	(Nestle)
95	Nutren 1.5	(Nestle)
96	Nutren 2.0	(Nestle)
97	NutrFocus	(Ross)
98	NutriFocus	(Ross)
99	NutriHeal	(Nestle)
100	NutriHep	(Nestle)
101	NutriMil Plus	(Ross)
102	NutriRenal	(Nestle)
103	Nutrivent	(Nestle)
104	Optimental	(Ross)
105	Osmolite	(Ross)
106	Osmolite 1.2	(Ross)
107	Osmolite HN	(Ross)
108	Osmolite HN Plus	(Ross)
109	Oxepa	(Ross)
110	Peptamen	(Nestle)
111	Peptamen 1.5	(Nestle)
112	Peptamen VHP	(Nestle)
113	Peptamen w/FOS/Inulin	(Nestle)
114	Peptinex	(Novartis)
115	Peptinex DT	(Novartis)
116	Perative	(Ross)
117	Polycose Powder/Liquid (CHO)	(Mead Johnson)
118	Portagen (MCT)	(Mead Johnson)
119	ProBalance	(Nestle)
120	Promod (Whey Protein)	(Ross)
121	Promote	(Ross)
122	Promote w/Fiber	(Ross)
123	ProPass (Protein)	(Hormel)
124	Pro-Peptide	(Hormel)
125	Pro-Peptide VHN	(Hormel)
126	ProRight (Egg Albumin)	(IFP)
127	Prosure	(Ross)
128	Protain XL	(Mead Johnson)
129	Pulmocare	(Ross)
130	Re/Neph	(Ross)
131	Re/Neph low Sugar	(Ross)

## Tube Feeding/Oral Nutrition Codes (continued)

132	Reabilan HN	(Nestle)
133	Renacal	(Nestle)
134	Replete	(Nestle)
135	Replete w/Fiber	(Nestle)
136	ReSource Arginaid (arginine powder)	(Novartis)
137	ReSource Arginaid Extra	(Novartis)
138	ReSource Benecalorie (Protein and fat)	(Novartis)
139	ReSource Benefiber (fiber)	(Novartis)
140	ReSource Beneprotein (Protein)	(Novartis)
141	ReSource Broth Plus Mix	(Novartis)
142	ReSource Diabetic	(Novartis)
143	ReSource Diabetishield	(Novartis)
144	ReSource Egg Nog Mix	(Novartis)
145	ReSource Fruit Bev	(Novartis)
146	ReSource Gelatin Plus Mix	(Novartis)
147	ReSource GlutaSolve (glutamine Powder)	(Novartis)
148	ReSource HealthShake No Sugar Added	(Novartis)
149	ReSource Instant Breakfast Mix	(Novartis)
150	ReSource Milkshake Mix	(Novartis)
151	ReSource Nutritious Juice Drink	(Novartis)
152	ReSource Plus	(Novartis)
153	ReSource Shake	(Novartis)
154	ReSource Shake Plus	(Novartis)
155	ReSource Standard	(Novartis)
156	Respalor	(Mead Johnson)
157	Restore-X (Amino Acids)	(Cambridge Nutraceuticals)
158	Sandosource Peptide	(Novartis)
159	Scandishake	(Scandipharm)
160	Subdue	(Mead Johnson)
161	Subdue Plus	(Mead Johnson)
162	Suplena	(Ross)
163	Tolerex	(Novartis)
164	TraumaCal	(Mead Johnson)
165	TwoCal HN	(Ross)
166	TwoCal HN	(Ross)
167	UltraCal	(Mead Johnson)
168	UltraCal HN Plus	(Mead Johnson)
169	Unifiber (Fiber)	(Niche Pharm)
170	VHC 2.25	(Nestle)
171	Vital HN	(Ross)
172	Vivonex Plus	(Novartis)
173	Vivonex RTF	(Novartis)
174	Vivonex T.E.N.	(Novartis)
175	Novasource	(Novartis)

## Tube Feeding/Oral Nutrition Codes (continued)

176	Novasource 2.0	(Novartis)
177	Promix	(Corpak)
178	10% Dextrose in Water (D10W)	
179	Arginaid	(Resource)
180	Sympt•X G.I.	(Baxter)
181	Osmolite 1.5	(Ross)
182	ProStat 64 (liquid protein) Carb Free	(Medical Nutrition)
183	ProStat 101 Enhanced Calories	(Medical Nutrition)
184	ProStat 121 Low Viscosity	(Medical Nutrition)
185	ProStat 150 High Calorie	(Medical Nutrition)
186	Re/Gen	(Ross)
187	Re/Gen low sugar	(Ross)
188	L-Arginaid	(Hormel)
189	Jevity 1 Cal	(Ross)
190	Jevity 1.2 Cal	(Ross)
191	Carnation Instant Breakfast (Lactose free)	(Nestle)
192	Carnation Instant Breakfast (Lactose free Plus)	(Nestle)
193	Carnation Instant Breakfast (Lactose free VHC)	(Nestle)
194	Scandishake	(Axcan)
195	Hi Cal	(Ross)
196	Hormel Solutions Nutritional Juice Drink	(Hormel)
197	Plus 2	(Hormel)
198	L-Emental Arg	(Hormel)
199	L-Emental Glut	(Hormel)
200	ProSource	(National Nutrition)
999	Other	

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## I. Tube Feeding/Oral Nutrition Codes - Alphabetized

### Code

01	Additions	(Nestle)
02	Advera (Fat malabsorbtion)	(Ross)
03	Alitraq	(Ross)
04	AltraQ	(Ross)
179	Arginaid	(Resource)
05	BOOST	(Mead Johnson)
06	BOOST Breeze	(Mead Johnson)
07	BOOST Hi Pro Powder	(Mead Johnson)
08	BOOST High Protein	(Mead Johnson)
09	BOOST High Protein Powder	(Mead Johnson)
10	BOOST Plus	(Mead Johnson)
11	BOOST w/Fiber	(Mead Johnson)
12	Carnation Instant Breakfast	(Nestle)
191	Carnation Instant Breakfast (Lactose Free)	(Nestle)
192	Carnation Instant Breakfast (Lactose Free Plus)	(Nestle)
193	Carnation Instant Breakfast (Lactose Free VHC)	(Nestle)
13	Casec (Protein)	(Mead Johnson)
14	Choice DM Beverage	(Mead Johnson)
15	Choice DM TF	(Mead Johnson)
16	Compleat	(Novartis)
17	Compleat Pediatric	(Novartis)
18	Comply	(Mead Johnson)
19	Criticare HN	(Mead Johnson)
20	Crucial	(Nestle)
21	Deliver 2.0	(Mead Johnson)
22	DiabetaSource	(Novartis)
23	DiabetaSource AC	(Novartis)
24	Diabetisource AC	(Novartis)
25	Enlive!	(Ross)
26	Ensure	(Ross)
27	Ensure Fiber w/FOS	(Ross)
28	Ensure High Calcium	(Ross)
29	Ensure High Protein	(Ross)
30	Ensure Light	(Ross)
31	Ensure Plus	(Ross)
32	Ensure Plus HN	(Ross)

**Tube Feeding/Oral Nutrition Codes - Alphabetized (Continued)**

33	Ensure Plus HN	(Ross)
34	Ensure Powder	(Ross)
35	Ensure Powder	(Ross)
36	Epular (Milk Protein, Soybean Oil)	(VistaPharm)
37	Equalyte	(Ross)
38	f.a.a.	(Nestle)
39	FiberBasics	(Hormel)
40	Fibersource HN	(Novartis)
41	Fibersource Standard	(Novartis)
42	Forta Drink	(Ross)
43	Forta Shake Powder	(Ross)
44	Glucerna	(Ross)
45	Glucerna Shake	(Ross)
46	Glutasorb	(Hormel)
47	Glutsorb	(Hormel)
48	Glytrol	(Nestle)
49	Great Shakes	(Hormel)
195	Hi Cal	(Ross)
50	Hormel Instant Soluble Fiber (Fiber)	(Hormel)
196	Hormel Solutions Nutritional Juice Drink	(Hormel)
51	HyFiber (Fiber)	(National Nutrition)
52	Immun-Aid	(McGaw)
53	Impact	(Novartis)
54	Impact 1.5	(Novartis)
55	Impact Glutamine	(Novartis)
56	Impact Recover	(Novartis)
57	Impact w/Fiber	(Novartis)
58	IntensiCal	(Mead Johnson)
59	Introlite	(Ross)
60	Isocal	(Mead Johnson)
61	Isocal HN	(Mead Johnson)
62	Isocal HN Plus	(Mead Johnson)
63	Isosource 1.5	(Novartis)
64	Isosource HN	(Novartis)
65	Isosource Standard	(Novartis)
66	Isosource VHN	(Novartis)

**Tube Feeding/Oral Nutrition Codes - Alphabetized (Continued)**

67	Jevity	(Ross)
68	Jevity Plus	(Ross)
189	Jevity 1 Cal	(Ross)
190	Jevity 1.2 Cal	(Ross)
69	Kemps Plus	(Hormel )
70	L -Argiment (L-Glu and L-Arg)	(National Nutrition)
188	L -Arginaid	(Hormel)
198	L -Emental Arg	(Hormel)
199	L -Emental Glu	(Hormel)
71	Lipasorb (Whole Protein/High MCT)	(Mead Johnson)
72	Magnacal Renal	(Mead Johnson)
73	MCT Oil (MCT)	(Mead Johnson)
74	Med Pass 2.0	(Hormel)
75	Meritene (Protein)	(Novartis)
76	Microlipid (50% Safflower Oil)	(Mead Johnson)
77	Mighty Shakes	(Hormel)
78	Mighty Shakes No Sugar Added	(Hormel)
79	Moducal Powder (Maltodextrin)	(Mead Johnson)
80	Modulen IBD	(Nestle)
81	Nepro	(Ross)
82	Nestle VHC 2.23	(Nestle)
175	Novasource	(Novartis)
176	Novasource 2.0	(Novartis)
83	Novasource Pulmonary	(Novartis)
84	Novasource Renal	(Novartis)
85	NuBasics	(Nestle)
86	NuBasics Juice Drink	(Nestle)
87	NuBasics Plus	(Nestle)
88	NuBasics VHP	(Nestle)
89	Nutrament	(Mead Johnson)
90	NutraShake Egg/Pro	(Ross)
91	NutraShake HiCal	(Ross)
92	NutraShake Juice/Fiber	(Ross)
93	Nutren 1.0	(Nestle)
94	Nutren 1.0 w/Fiber	(Nestle)
95	Nutren 1.5	(Nestle)

### Tube Feeding/Oral Nutrition Codes - Alphabetized (Continued)

96	Nutren 2.0	(Nestle)
97	NutrFocus	(Ross)
98	NutriFocus	(Ross)
99	NutriHeal	(Nestle)
100	NutriHep	(Nestle)
101	NutriMil Plus	(Ross)
102	NutriRenal	(Nestle)
103	Nutrivent	(Nestle)
104	Optimental	(Ross)
105	Osmolite	(Ross)
106	Osmolite 1.2	(Ross)
181	Osmolite 1.5	(Ross)
107	Osmolite HN	(Ross)
108	Osmolite HN Plus	(Ross)
109	Oxepa	(Ross)
110	Peptamen	(Nestle)
111	Peptamen 1.5	(Nestle)
112	Peptamen VHP	(Nestle)
113	Peptamen w/FOS/Inulin	(Nestle)
114	Peptinex	(Novartis)
115	Peptinex DT	(Novartis)
116	Perative	(Ross)
197	Plus 2	(Hormel)
117	Polycose Powder/Liquid (CHO)	(Mead Johnson)
118	Portagen (MCT)	(Mead Johnson)
119	ProBalance	(Nestle)
177	Promix	(Corpak)
120	Promod (Whey Protein)	(Ross)
121	Promote	(Ross)
122	Promote w/Fiber	(Ross)
123	ProPass (Protein)	(Hormel)
124	Pro-Peptide	(Hormel)
125	Pro-Peptide VHN	(Hormel)
126	ProRight (Egg Albumin)	(IFP)
200	ProSource	(National Nutrition)
182	ProStat 64 (liquid protein) Carb Free	(Medical Nutrition)

**Tube Feeding/Oral Nutrition Codes - Alphabetized (Continued)**

183	ProStat 101 Enhanced Calorie	(Medical Nutrition)
184	ProStat 121 Low Viscosity	(Medical Nutrition)
185	ProStat 150 High Calorie	(Medical Nutrition)
127	Prosure	(Ross)
128	Protain XL	(Mead Johnson)
129	Pulmocare	(Ross)
186	Re/Gen	(Ross)
187	Re/Gen low sugar	(Ross)
130	Re/Neph	(Ross)
131	Re/Neph low Sugar	(Ross)
132	Reabilan HN	(Nestle)
133	Renacal	(Nestle)
134	Replete	(Nestle)
135	Replete w/Fiber	(Nestle)
136	ReSource Arginaid (arginine powder)	(Novartis)
137	ReSource Arginaid Extra	(Novartis)
138	ReSource Benecalorie (Protein and fat)	(Novartis)
139	ReSource Benefiber (fiber)	(Novartis)
140	ReSource Beneprotein (Protein)	(Novartis)
141	ReSource Broth Plus Mix	(Novartis)
142	ReSource Diabetic	(Novartis)
143	ReSource Diabetishield	(Novartis)
144	ReSource Egg Nog Mix	(Novartis)
145	ReSource Fruit Bev	(Novartis)
146	ReSource Gelatin Plus Mix	(Novartis)
147	ReSource GlutaSolve (glutamine Powder)	(Novartis)
148	ReSource HealthShake No Sugar Added	(Novartis)
149	ReSource Instant Breakfast Mix	(Novartis)
150	ReSource Milkshake Mix	(Novartis)
151	ReSource Nutritious Juice Drink	(Novartis)
152	ReSource Plus	(Novartis)
153	ReSource Shake	(Novartis)
154	ReSource Shake Plus	(Novartis)
155	ReSource Standard	(Novartis)
156	Respalor	(Mead Johnson)
157	Restore-X (Amino Acids)	(Cambridge Nutraceuticals)
158	Sandosource Peptide	(Novartis)

**Tube Feeding/Oral Nutrition Codes - Alphabetized (Continued)**

159	Scandishake	(Scandipharm)
194	Scandishake	(Axcan)
160	Subdue	(Mead Johnson)
161	Subdue Plus	(Mead Johnson)
162	Suplena	(Ross)
180	Sympt *X G.I.	(Baxter)
163	Tolerex	(Novartis)
164	TraumaCal	(Mead Johnson)
165	TwoCal HN	(Ross)
166	TwoCal HN	(Ross)
167	UltraCal	(Mead Johnson)
168	UltraCal HN Plus	(Mead Johnson)
169	Unifiber (Fiber)	(Niche Pharm)
170	VHC 2.25	(Nestle)
171	Vital HN	(Ross)
172	Vivonex Plus	(Novartis)
173	Vivonex RTF	(Novartis)
174	Vivonex T.E.N.	(Novartis)
178	10% Dextrose in Water (D10W)	
999	Other	

## J. Catheter Codes

<b><u>Code</u></b>	<b><u>Manufacturer</u></b>	<b><u>MODEL</u></b>	<b><u>SIZE</u></b>	<b><u>TYPE</u></b>
01.	AngioDynamics	More-Flow	14.5 x 24 cm	Straight
02.	AngioDynamics	More-Flow	14.5 x 28 cm	Straight
03.	AngioDynamics	More-Flow	14.5 x 32 cm	Straight
04.	AngioDynamics	More-Flow	14.5 x 36 cm	Straight
05.	AngioDynamics	More-Flow	14.5 x 40 cm	Straight
06.	AngioDynamics	More-Flow	14.5 x 24 cm	Pre-Curve
07.	AngioDynamics	More-Flow	14.5 x 28 cm	Pre-Curve
08.	AngioDynamics	More-Flow	14.5 x 32 cm	Pre-Curve
09.	AngioDynamics	More-Flow	14.5 x 36 cm	Pre-Curve
10.	AngioDynamics	Dura-Flow	15.5 x 24 cm	Straight
11.	AngioDynamics	Dura-Flow	15.5 x 28 cm	Straight
12.	AngioDynamics	Dura-Flow	15.5 x 32 cm	Straight
13.	AngioDynamics	Dura-Flow	15.5 x 36 cm	Straight
14.	AngioDynamics	Dura-Flow	15.5 x 40 cm	Straight
15.	AngioDynamics	Schon XL Acute	15 cm	
16.	AngioDynamics	Schon XL Acute	20 cm	
17.	AngioDynamics	Schon XL Acute	24 cm	
18.	Arrowgard	Blue Catheters	14 Fr x 6" (15cm)	Curved Two-Lumen
19.	Arrowgard	Blue Catheters	14 Fr x 6" (15cm)	Two-Lumen
20.	Arrowgard	Blue Catheters	14 Fr x 8" (20cm)	Curved Two-Lumen
21.	Arrowgard	Blue Catheters	14 Fr x 8" (20cm)	Two-Lumen
22.	Arrowgard	Blue Catheters	14 Fr x 5-1/8" (13cm)	Two-Lumen
23.	Arrowgard	Acute Catheters	12 Fr x 6" (16cm)	Two-Lumen
24.	Arrowgard	Acute Catheters	12 Fr x 8" (20cm)	Two-Lumen
25.	Bard Hickman	Apheresis	13.5 Fr x 28 cm	Chronic Dual Lumen
26.	Bard Hickman	Apheresis	13.5 Fr x 36 cm	Chronic Dual Lumen
27.	Bard Hickman	Apheresis	13.5 Fr x 40 cm	Chronic Dual Lumen
28.	Bard Hickman	Apheresis	13.5 Fr x 45 cm	Chronic Dual Lumen
29.	Bard Hickman	Apheresis	13.5 Fr x 50 cm	Chronic Dual Lumen
30.	Bard Hickman	Apheresis	13.5 Fr x 55 cm	Chronic Dual Lumen
31.	Bard Hickman	Apheresis	13.5 Fr x 60 cm	Chronic Dual Lumen
32.	Bard Hickman	Apheresis	13.5 Fr x 70 cm	Chronic Dual Lumen
33.	Bard Niagra	Acute	13.5 Fr x 12.5 cm	Pre-Curved Dual Lumen
34.	Bard Niagra	Acute	13.5 Fr x 15 cm	Pre-Curved Dual Lumen

<b><u>Code</u></b>	<b><u>Manufacturer</u></b>	<b><u>MODEL</u></b>	<b><u>SIZE</u></b>	<b><u>TYPE</u></b>
35.	Bard Niagra	Acute	13.5 Fr x 20 cm	Pre-Curved Dual Lumen
36.	Bard Niagra	Acute	13.5 Fr x 15 cm	Straight Dual Lumen
37.	Bard Niagra	Acute	13.5 Fr x 20 cm	Straight Dual Lumen
38.	Bard Niagra	Acute	13.5 Fr x 24 cm	Straight Dual Lumen
39.	Bard	HemoGlide	14.5 Fr x 19 cm	Curved Dual Lumen
40.	Bard	HemoGlide	14.5 Fr x 24 cm	Curved Dual Lumen
41.	Bard	HemoGlide	14.5 Fr x 28 cm	Curved Dual Lumen
42.	Bard	HemoGlide	14.5 Fr x 31 cm	Curved Dual Lumen
43.	Bard	Flexxicon II Acute	12.5 cm	Pre-Curved Dual Lumen
44.	Bard	Flexxicon II Acute	15 cm	Pre-Curved Dual Lumen
45.	Bard	Flexxicon II Acute	20 cm	Pre-Curved Dual Lumen
46.	Bard	Flexxicon II Acute	15 cm	Straight Dual Lumen
47.	Bard	Flexxicon II Acute	20 cm	Straight Dual Lumen
48.	Bard	Flexxicon II Acute	24 cm	Straight Dual Lumen
49.	Boston Scientific	Vaxcel Tunneled Dialysis		Dual Lumen
50.	Boston Scientific	Vaxcel Tunneled Dialysis		Dual Lumen
51.	Boston Scientific	Vaxcel Tunneled Dialysis		Dual Lumen
52.	Deltec	Long term Hemodialysis	12.5 Fr x 24 cm	Dual Lumen
53.	Deltec	Long term Hemodialysis	12.5 Fr x 28 cm	Dual Lumen
54.	Deltec	Long term Hemodialysis	12.5 Fr x 32 cm	Dual Lumen
55.	Deltec	Short term Demodialysis	11.5 Fr x 12 cm	Dual Lumen
56.	Deltec	Short term Demodialysis	11.5 Fr x 15 cm	Dual Lumen
57.	Deltic	Short term Demodialysis	11.5 Fr x 20 cm	Dual Lumen
58.	Horizon Circle-C	Hemodialysis/Apheresis	13.5 Fr x 36 cm	Dual Lumen
59.	Horizon Circle-C	Hemodialysis/Apheresis	13.5 Fr x 40 cm	Dual Lumen
60.	Horizon Circle-C	Hemodialysis/Apheresis	13.5 Fr x 45 cm	Dual Lumen
61.	Horizon Circle-C	Acute Hemodialysis	12 Fr x 15 cm	Dual Lumen
62.	Horizon Circle-C	Acute Hemodialysis	12 Fr x 20 cm	Dual Lumen
63.	Kendall	Mahurkar	10 Fr x 15 cm	Curved Dual Lumen
64.	Kendall	Mahurkar	11.5 Fr x 13.5 cm	Curved Dual Lumen
65.	Kendall	Mahurkar	11.5 Fr x 16 cm	Curved Dual Lumen
66.	Kendall	Mahurkar	11.5 Fr x 19.5 cm	Curved Dual Lumen

<b><u>Code</u></b>	<b><u>Manufacturer</u></b>	<b><u>MODEL</u></b>	<b><u>SIZE</u></b>	<b><u>TYPE</u></b>
67.	Kendall	Mahurkar	13.5 Fr x 36 cm	Curved Cuffed
68.	Kendall	Mahurkar	13.5 Fr x 40 cm	Curved Cuffed
69.	Kendall	Mahurkar	13.5 Fr x 45 cm	Curved Cuffed
70.	Kendall	Mahurkar	13.5 Fr x 50 cm	Curved Cuffed
71.	Kendall	Mahurkar	11.5 Fr x 13.5 cm	Straight Ext. Dual Lumen
72.	Kendall	Mahurkar	11.5 Fr x 16 cm	Straight Ext. Dual Lumen
73.	Kendall	Mahurkar	11.5 Fr x 19.5 cm	Straight Ext. Dual Lumen
74.	Kendall	Mahurkar	11.5 Fr x 24 cm	Straight Ext. Dual Lumen
75.	Kendall	Mahurkar	12 Fr x 13 cm	Triple Lumen
76.	Kendall	Mahurkar	12 Fr x 16 cm	Triple Lumen
77.	Kendall	Mahurkar	12 Fr x 20 cm	Triple Lumen
78.	Kendall	Mahurkar	12 Fr x 24 cm	Triple Lumen
79.	Medcomp	Hemo-Cath	8 Fr x 12 cm	Double Lumen
80.	Medcomp	Hemo-Cath	11.5 Fr x 15 cm	Double Lumen
81.	Medcomp	Hemo-Cath	11.5 Fr x 20 cm	Double Lumen
82.	Medcomp	Hemo-Cath	11.5 Fr x 24 cm	Double Lumen
83.	Kendall	Quinton	8 Fr x 12 cm	Straight Single
84.	Kendall	Quinton	8 Fr x 15 cm	Straight Single
85.	Kendall	Quinton	8 Fr x 19.5 cm	Straight Single
86.	Kendall	Quinton	8 Fr x 25 cm	Straight Single
87.	Kendall	Quinton	8 Fr x 15 cm	Curved
88.	Kendall	Quinton Permacath	12 Fr x 35 cm	Swan Neck
89.	Kendall	Quinton Permacath	12 Fr x 38 cm	Swan Neck
90.	Kendall	Quinton Permacath	12 Fr x 41 cm	Swan Neck
91.	Kendall	Quinton Permacath	12 Fr x 43 cm	Swan Neck
92.	Kendall	Quinton Permacath	12 Fr x 49 cm	Swan Neck
99.	Other			

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**K. Infection Sites**

<b><u>Code</u></b>	<b><u>Infection Site</u></b>
01	Dialysis catheter exit site
02	Dialysis catheter associated bacteremia
03	Non-dialysis catheter exit site
04	Non-dialysis catheter associated bacteremia
05	Endocarditis
06	Bacteremia, source unknown
07	Meningitis
08	Pneumonia
09	Empyema
10	Peritonitis
11	Cholecystitis
12	Intra-abdominal infection, other
13	Pyelonephritis
14	Urinary tract infection
15	Surgical wound infection
16	Cellulitis
17	Osteomyelitis
18	Septic arthritis
19	Sinus infection
20	Soft tissue infection
99	Other

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