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Modification of Diet in Renal Disease Study

GENERAL INSTRUCTIONS

The following instructions should be followed
in completing all MDRD Data Forms

- o Use a black ballpoint pen. Forms will be kept at the Clinical Centers. For designated forms, a copy will be sent to the Central Laboratories or to the Nutrition Coordinating Center.
- o As of September 1989 you no longer send a hard copy of paper forms to the DCC (except Informed Consents and EKG strips and Form 18's). Most forms are no longer printed on NCR paper.
- o All letters should be printed and capitalized.
- o Consult the Forms Instructions in the Manual of Operations when having difficulty completing any item. If this does not answer your question, contact the Data Coordinating Center (or, if it is a Nutrition Form, contact the Nutrition Coordinating Center).
- o Any forms which the patient completes must be reviewed before they can be transmitted or mailed. Examine these forms to make sure they have been completed properly and that the writing is legible.
- o When all of a patient's forms for a visit have been completed, check for consistency within and between the forms. Make sure they are all complete and that the Patient Identification Number is the same on each form.
- o Comments may be included on the forms as long as they do not obscure any area of the form that is to be entered. These comments will not be entered into the computer.

Modification of Diet in Renal Disease Study

CODING RULES

- o Whenever dashes are provided for an entry, the data should be right justified. The data items should also be zero filled, i.e., any unused dashes should be filled in with "0's".

Example 1. Given four dashes, the value 536 would be filled in as follows.

0 _5_ _3_ _6_

Right justify. Do NOT fill it in like this.

5 _3_ _6_ _

- o Enter only one character in each dash.
- o Round off values after a decimal point to fit into the space given. Do NOT add dashes, and do NOT move a decimal point.

Example 2. Given four dashes, decimal point, one dash, the value 123.67 should be entered as follows. If the last digit is a 5, round to the nearest even number for the second to last digit. (e.g., 123.45 = 123.4 and 123.55 = 123.6)

0 _1_ _2_ _3_ . _7_

Do NOT add dashes.

0 _1_ _2_ _3_ . _6_ ⁷_

- o The decimal point is always assumed to be at the far right if it is not included on the form. Do not add a decimal point.

Example 3. Given five dashes, the value 123.67 should be entered as follows.

0 _0_ _1_ _2_ _4_

- o When a value is too large to fit in the number of dashes provided, a "-1" should be written in the dashes. The correct data should be written in the margin of the paper form but the "-1" should be entered into the computer. Whenever this situation occurs, the Study Coordinator, Dietitian, or MDRD Tech must complete a "Data Out of Range" form.

Modification of Diet in Renal Disease Study

CODING RULES

- o While you are entering data into the computer, if you find an error on a form: 1) If you know the correct response, fix it on the form and enter the correct response in the computer. Make sure you notify everyone who reviewed the form that you found and corrected an error. 2) If you do not know the correct response, do not work any further on that form and do not transmit it to the Data Coordinating Center. Proceed with your other forms and find and enter the correct response later. Refer to Manual of Operations for details on the Datalex procedures.

- o After a form has been entered into the computer and transmitted, if you find you must make any correction to your paper copy of the form, notify the Data Coordinating Center by completing a Data Change Form (Form 25), and transmitting it to the DCC. They can then change the study data base and fix their paper version of your form.

Form and Patient Identification

- o The form identification data must be complete on the top of the first page of each form. The Study Coordinator is responsible for making sure this data is present on all forms, including those which the patient completes. The dietitian should review nutrition forms submitted for data entry.

- o The Patient Identification Number should be entered on the first page and copied at the top of each page. This is important in case a staple bends and a form comes apart.

- o The Name Code consists of the first two letters of a patient's first name and the first two letters of the patient's last name.

- o In instances where more than one person at a center would have the same namecode, the center personnel should adjust one of them in any way they would like, so no duplicate namecodes within a center exist.

- o The clinical center code list follows:
 - 01 = Bowman Gray School of Medicine
 - 02 = Brigham and Women's Hospital/Beth Israel Hospital
 - 03 = Brookdale Hospital Medical Center
 - 04 = Duke University School of Medicine
 - 05 = Emory University
 - 06 = George Washington University Medical Center
 - 07 = Harbor Medical Center

Modification of Diet in Renal Disease Study

CODING RULES

- 08 = New England Medical Center Hospital/
Massachusetts General Hospital
- 09 = Ohio State University Hospitals
- 10 = University of Florida
- 11 = University of Iowa Hospital and Clinics
- 12 = University of Miami Jackson Memorial Medical Center
- 13 = University of Southern California
- 14 = University of Texas Health Science Center
- 15 = Vanderbilt University Medical Center

- o Dates should always be entered as month/day/year. Be sure to right justify and zero fill the dates as described above, so each element has two digits (MM/DD/YY). When entering a birth date, be especially careful not to enter the current year. This is a common mistake.
- o Dates must always be complete. If the month is unknown, fill in a 06. If a day is unknown, fill in a 15. If year is unknown, leave blank.
- o Certification numbers will be assigned and must be entered in the appropriate spaces at the end of each form.
- o Visit Type will appear on many forms. The choices are as follows:

S = Screening

B = Baseline

F = Follow-Up

A = Abbreviated follow-up

(Patients who have reached stop points)

P = At time of stop point.

This should only be used on all forms completed when a stop point is reached. Following this, visits at 4 month intervals will be labelled A.

X = Study F Follow-Up

C = Close-Out Visit

Z = Post Close-Out Visit

- o Notice the E ___
V ___
T ___

at the top of each form. It is there as a checklist to indicate when a form has been Entered, Verified and Transmitted. This is optional and will not be entered.

- o For some questions where 'other' is a category up to 20 digits of the comment area can and should be coded in the computer when 'other' is specified. "20 characters maximum" is written beside those 'other's' that may be entered.

If you have any problems or general concerns related to completing the data forms, contact the Data Coordinating Center by telephone or electronic mail.

**M D R D
VISIT TYPES AND NUMBERS**

	<u>VIST</u>	<u>VISN</u>
1. Screening if patient screened multiple times use 2.0, 3.0, etc...	S	1.0
2. Baseline BOA Nutrition record data	B	0.0 0.5 1.0 2.0 3.0
if BP or albumin repeated for eligibility 3.9 (Forms 17, 33, or 46)		
3. Follow-Up F1A Nutrition data	F	1.0 1.5 2.0 2.5 3.0 4.0 .
F2A Nutrition data		.
		48.0
4. Post Stop point at the time of a stop, blood work	P	1.0 (Forms 6, 17, 33, 16, 19)
similar to an F4 visit & GFR should be done. No form 5.		
5. Abbreviated FU	A	4.0 8.0 12.0 . . .
		48.0
Procedures for patients done after a stoppoint is reached. The schedule is every 4th month (so original appointment schedule is accurate) so no 'off' (F5, F11) visits should occur.		
6. Study F	X	6.0 12.0 18.0 24.0 .
		48.0
7. Close Out Details will follow.	C	
8. Post Close-Out Details will follow.	Z	
9. Study C follow-up	K	

List of "Others" which can be Entered
(20 Characters may be entered)

<u>Form #</u>	<u>Description</u>	<u>Item #</u>	<u>Description</u>
1	Chart Review	Q05B Q06	Other Source of Referral Other Renal Diagnosis
3	Screening Form	Q06 Q12M	Other Renal Diagnosis Other Reason - Doubtful Compliance
4	Baseline 0	Q06 Q10 Q14A Q14B Q18A	Other Referral Source Other Race Other Employment Status Other Employment Status Other Religion
5	Monthly Visits	Q05B	Other Reason Missed Visits
7	Renal Diagnosis	Q05 Q06P	Other Renal Diagnosis Other Evidence for Diagnosis
8	Secondary Screen	Q05L Q09L Q16	Other Reason for Dropping Other Reason - Doubtful Compliance Other Factors Preventing Randomization
11	Stop Point	Q11 Q14F	Other Serious Med. Conditions Other Diet Therapy
12	Abbreviated FU	Q13E	Other Diet Therapy
13	Annual FU	Q08A Q12A	Other Employment Status Other Religion
14	Reason Missed	Q16	Reason for Missed Visits
15	Death	Q05 Q07	Other Cause of Death Other Location of Death
23	Action Items	Q05-10	Steps Taken to Resolve
26	Patient Symptoms	Q28	Other Unexpected Symptoms
32	Central Urine	Q8-9	Comments
33	Central Blood	Q24-25	Comments
35	EKG Results	Q12 Q17	Other Rhythm Other Abnormalities
41	Death Review	Q05	Other Cause of Death

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List of "Others" which can be Entered
(20 Characters may be entered)

<u>Form #</u>	<u>Description</u>	<u>Item #</u>	<u>Description</u>
50	Recruitment Data for Pts. in Baseline Q04		Person First Hears About Study; Other
71	Study Diet Rx	Q05F Q10C Q11B Q14C	Rationale for Tot. Calorie Rx Other Na Adjustment Other Alcohol Int. Adjust. Other % of Cals. Adjust.
72	Special Diet Consid.	Q10C Q12C Q20B	Other Reason Calorie Adjust. Other Altered Na Rx Adjust. Other Dietary Adjust.
79	Special Food Products Order Form	Q05N Q05O Q05P Q05Q	Other Products Code #1 Other Products Code #2 Other Products Code #3 Other Products Code #4

0.5.2.1

ENVIRYPOINT 90 ALLOWABLE RANGES
(Forms completed at Clinical Centers)

<u>Form #</u>	<u>Item #</u>	<u>Description</u>	<u>Ranges</u>
3	Q19A	Height (cm)	120.0 - 200.0
	Q19B	Elbow Width (cm)	5.0 - 9.0
	Q19D-E	Body Weight (kg)	40.0 - 130.0
		Creatinines (mg/dl)	0.1 - 15.0
	Q18B	Albumin (g/dl)	0.0 - 8.0
4	Q38A	Height (cm)	120 - 200
	Q38B	Elbow Width (cm)	5.0 - 9.0
	Q38D	Body Weight (kg)	40.0 - 130.0
	Q14E	Days Missed at Work	0 - 365
	Q31	Packs per Day	0 - 20.00
5	Q07	Packs per Day	0 - 20.00
	Q09A	Body Weight (kg)	40 - 130
6	Q05	Creatinine	0.1 - 15.0
		Urea Nitrogen	10 - 180
		Sodium	30 - 450
		Potassium	3.0 - 7.0
		Chloride	80 - 130
		Bicarbonate	10 - 50
		Glucose	1 - 900
		Calcium	6.0 - 12.0
		Iron	10 - 220
	Q06	Magnesium	1.0 - 5.0
		WBC	2.0 - 15.0
	Q07A	Hemoglobin	6.0 - 20.0
		Hematocrit	20.0 - 60.0
	Hours Fasting	0 - 40, 99	
12	Q06	Body Weight (kg)	40.0 - 130.0
13	Q08D	Days Missed from Work	0 - 366
	Q10B	Number of People Supported	0 - 20
	Q15	Height (cm)	120.0 - 200.0
17	Q07B	Number of Hours Fasting	0 - 40, 99
19	Q06	Number of Hours Fasting	0 - 40, 99
20	Q05	Urea Nitrogen	10 - 180
		Creatinine	0.1 - 15.0
		Calcium	6.0 - 12.0
		Magnesium	1.0 - 5.0

ENTRYPOINT 90 ALLOWABLE RANGES
(Forms completed at Clinical Centers)

<u>Form #</u>	<u>Item #</u>	<u>Description</u>	<u>Ranges</u>
21		NO RANGE CHECKS - BE CAREFUL	
26	—	Number of Days in Past Month	0 - 60
46		Systolic	40 - 290
		Diastolic	40 - 290
		Pulse Obliteration	40 - 250
		Maximum Random Zero	0 - 50
47	Q12A	Body Weight (kg)	40.0 - 130.0
	Q13A	Systolic BP	100 - 220
		Diastolic BP	0 - 150
	Q14A	Creatinine	0.1 - 15.0
	Q15A	Albumin	2.0 - 6.0
	Q16	Body Weight (kg)	40.0 - 130.0
65	Q6	Upper Arm Circumference (cm)	10.0 - 50.0, 60.0, 70.0
	Q7	Triceps (mm)	2.0 - 50.0, 60.0, 70.0
	Q8	Biceps (mm)	2.0 - 50.0, 60.0, 70.0
	Q10	Subscapular (mm)	5.0 - 50.0, 60.0, 70.0
	Q11	Weight (kg)	40.0 - 130.0
	Q12	Height (cm)	120.0 - 200.0
	Q13	Elbow Width (cm)	5.0 - 9.0
70	Q5C	Average Protein Intake from 3-Day Food Record	0.40- 2.00
	Q5E	Usual Protein Intake	0.40- 2.00
	Q7B	Average Caloric Intake	800 -5000
	Q7D	Calorie Rx	1000 -5000
71	Q5F	Calorie Rx (kcal/day)	1000 -5000
	Q7B	Calcium Intake (mg/day)	50 -2000
	Q7D	Code Number	0 - 19
	Q10D	Sodium (mg/day)	≥ 1000
	Q12B	Potassium (mg/day)	900 -6000
	Q13B	Phosphorus (mg/day)	200 -2000
	Q14D	% from Fat	≤ 60
	Q14E	% from Carbohydrates	≥ 40
	Q7E	Dosage of Elemental Calcium per Tablet	100 - 800

ENTRYPOINT 90 ALLOWABLE RANGES
(Forms completed at Clinical Centers)

<u>Form #</u>	<u>Item #</u>	<u>Description</u>	<u>Ranges</u>
72	Q8B	Altered Protein Rx	0.400- 2.000
	Q8C	Portion that Must be HBV	0, 0.400- 2.000
	Q9B,C	Altered Phosphorus Rx	200 -2000
	Q10D	Altered Diet Calorie Rx	1000 -5000
	Q11C	Estimated Calcium Intake	50 -2000
	Q11D	Calcium Supplement Rx	50 -2000
	Q11E	Calcium Supplement Code No.	0 - 19
	Q11F	Dosage of Elemental Calcium per Tablet	0 - 900
	Q12D	Sodium Rx	≥ 1000
	Q14B	Altered Potassium Rx	900 -6000
	Q18B	Altered Percent of Calories from Fat	≤ 60
	Q19B	Altered Percent of Calories from Carbohydrates	≥ 30

**List of Forms to be Completed
When a Routine Visit is Missed**

Form 5 - Monthly Visit

- Form 16 - GFR Mailing
- Form 17 - Blood/Urine Mailing
- Form 18 - EKG Mailing
- Form 19 - Amino Acid Mailing

Complete any of the above forms for procedures which are required by the protocol at the visit which was missed.

Form 12 - Abbreviated Follow-Up after Stop Point

- Form 16 - GFR Mailing (except if dialysis or transplant stop point)
- Form 17 - Urine/Blood Mailing

Form 47 - Study F Form

- Form 17 - Blood Mailing (Only Blood)
- Complete this form ONLY when a visit is held**

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FORMS FOR MDRD TECHNICIANS TO BE PARTICULARLY AWARE OF
FROM VOLUME 2

<u>CLINICAL CENTER FORM #</u>	<u>RESULT FORM #</u>
16 - GFR Mailing	42
17 - Blood/Urine Mailing	32, 33
18 - EKG Mailing	35
19 - Amino Acid Mailing	36
6 - Local Lab Data	
46 - Blood Pressure	
20 - Local Lab QC	
21 - CAP QC	34, 39
22 - QC Matching	
24 - Data-Out-Of-Range	
25 - Data Change	

2.5.6

Modification of Diet in Renal Disease Study
OUTLINE OF EVENTS
(Corresponding to Non-Nutrition Forms)

Recruitment Form (Form #00)	To be completed for phone calls from patients inquiring about the study.
Chart Screening Form (Form #01)	Must be completed for all patients considered for a screening visit.
Screening Visits Not Done (Form #02)	Any patients meeting eligibility via a Chart Review who are eligible for a Screening Visit but do not have one, should be listed.
Screening Form (Form #03)	All patients who have an MDRD screening visit, should have this form completed.
Recruitment Data for Patients in Baseline (Form #50)	This should be done for all patients who have a screening visit. The title is erroneous since 3/1/90 it was decided to do for all screened patients whether they go on to Baseline or not.
Other Evidence of Renal Disease Form (Form #51)	This should be completed in addition to Form #3 when serum creatinine is too low, but the patient is still eligible since there is other evidence of renal disease.
Primary Informed Consent Form	All patients who meet the eligibility criteria in the Screening Period will be asked to complete this form and consent to enter the Baseline Period.
Demographic and Baseline (Form #04)	This form will be completed at the first clinic visit Form (Visit 0) during the baseline period for each patient.
Monthly Examination Form (Form #05)	Every month following the first baseline visit, (Visit 0), this form will be used to record data collected during scheduled monthly visits for the entire study period. It is required even if the visit is missed.
Local Laboratory Measurement Form (Form #06)	Local laboratory measurements done for purposes of the Study should be recorded here.
Local Blood Pressure Form (Form #46)	Complete at screening and every month when blood pressure is measured. Every 4 months in conjunction with Form 12 and annually with Form 47.

Modification of Diet in Renal Disease Study
Outline of Events

Renal Diagnosis Form (Form #07)	At Baseline Visit 1, this form will be completed for each patient to record renal diagnosis history.
Secondary Screening/Baseline Dropout Form (Form #08)	After Baseline Visit 3, this form will document any changes in eligibility prior to possible randomization. If a patient drops out prior to the end of aseline, use this form to record the reason.
Secondary Informed Consent	Those patients who still meet all eligibility requirements at the end of baseline will be asked to sign this form and consent to be randomized to a study diet.
Study A & B Randomization Form (DCC) (Form #37)	At the end of baseline, after consent forms are signed, each eligible patient will be randomized by the DCC to a blood pressure goal and a diet to be followed for the follow-up period of the study.
Randomization Form (Clinical Center) (Form #09)	When the patient has been randomized (over the phone), this form will be completed at the Clinical Center.
Unscheduled Medical Attention Form (Form #10)	Whenever a hospitalization occurs, this form must document the visit.
Stop Point Form (Form #11)	Whenever a stop point is reached, this form will document when and why.
Study C Informed Consent Form	Those patients who meet criteria to enter Study C will be asked to sign the appropriate form.
Study C Assignment Form (Form #31)	When a patient becomes part of Study C, this form should be completed.
Abbreviated Follow-Up Form (Form #12)	After a stop point has been reached, the patient will continue to be followed every four months (unless he/she becomes part of Study C). This form will replace the Monthly Exam Form for these patients.
Study F Form (Form #47)	This form should be completed every six months for Study F patients. It is used to follow-up on these patients.

Modification of Diet in Renal Disease Study
Outline of Events

Annual Follow-Up Form
(Form #13)

This form should be completed annually (at Follow-Up Visits #12, 24, 36, 48) in conjunction with the Monthly Examination Form, the Abbreviated Follow-up Form or the Study F Form. It contains demographic data similar to that collected initially.

Reason for Multiple Missed
Visit Form (Form #14)

This form should be completed if a patient has missed four or more consecutive follow-up visits to document reasons why patient missed visits.

Death Notification Form
(Form #15)

In the event of a death, this form will be completed as soon as information becomes available to document the event.

GFR Determination Work Sheet
Form (Form #16)

This will be completed and sent with samples to the Central Lab at the time of all GFR determinations. This form should be completed even if a required GFR was not done.

Central Laboratory Mailing
Form (Form #17)

This form should be completed by Clinical Center study technician or coordinator and sent with any blood or urine samples going to the Central Lab for analysis. It is required whenever samples should be sent, whether they were or not.

EKG Mailing Form
(Form #18)

An electrocardiogram will be done at Baseline 2 and annually thereafter (F11, F23,...). The EKG tracing and this form will be sent to the DCC, who will deliver it to the Central EKG Lab. Complete for ALL required EKG's whether done or not.

Amino Acid Mailing Form
(Form #19)

This form should be completed, transmitted and sent with all amino acid samples done for the Study. The number of hours fasting and the diet the patient is on should be documented on this form. It is required whenever samples should be sent whether they are or not.

Central Lab Urine Report Form
(Form #32)

This form includes central 24-Hour urine analysis results from the CBL.

Central Lab Blood Report Form
(Form #33)

The form includes all central blood measurement results.

Modification of Diet in Renal Disease Study
Outline of Events

Central Laboratory EKG Form (Form #35)	This form will be completed at the central EKG Lab with results of the EKG.
Amino Acid Data Form (Form #36)	The Central Amino Acid Lab personnel will complete this form for all analyses done.
Central Lab QC ID Matching Form (Form #22)	This form will record which real patient sample to match with QC ID data. It is completed by the Clinical Center and not communicated to the Central Lab.
Action Item Response Form (Form #23)	This form will detail efforts made at the centers to respond to each action item. It is completed monthly.
Data Out of Range Form (Form #24)	This form is to be used whenever a value is outside the Datalex Entrypoint 90 range and must be entered separately.
Data Change Form (Form #25)	Use this form to notify the DOC of any changes to be made to existent database entries.
Patient Symptom Form (Form #26)	This form is completed monthly by the patient starting at B0 to indicate symptoms the patients may be having.
Quality of Well Being (Form #27)	The Quality of Life Scale is used to record and measure to what degree patients' activities are limited by renal disease and its treatment. Completed at the DOC via phone interview.
Symptom Check List (Form #28)	This form is an inventory designed to reflect patient's psychological symptom patterns. It will be completed by the patient at the end of baseline, and every four months thereafter.
Economic Information Form (Form #29)	Complete this insurance information form at the Screening visit for all patients entering Baseline and annually thereafter.
Patient Transfer Form (Form #30)	In the event that a patient moves and becomes another study physician's patient, the destination center should complete this form.

Modification of Diet in Renal Disease Study
Outline of Events

Peer Group Range Form (Form #39)	The Central Biochemistry Lab will complete this form for each center to ease the reporting of CAP results.
Stop Point Review Form (Form #40)	This form will be completed with the consensus of the patient safety committee's review of each stop point.
Death Review Form (Form #41)	This form will be completed with the Patient Safety Committee's review of each patient's cause of death.
GFR Data Form (Form #42)	This is an example format of the data entered by the Central GFR Laboratory.
Leisure Time Physical Activity Form (Form #48)	To be completed annually (B1, F10, F22..) on all Studies A and B patients to record their assessment of activities.
Safety Variable Review Form (Form #38)	The Clinical Management Committee will be responsible for completing these forms when safety variables are reviewed.
Compliance Committee Review Form (Form #49)	It will be completed for each compliance action item reviewed by the committee.
Other Evidence of Renal Disease Form (Form #51)	This should be completed in addition to Form #3 when serum creatinine is too low, but the patient is still eligible since there is other evidence of renal disease.

NUTRITION RELATED FORMS

<u>Form #</u>	<u>Description</u>	<u>Who Completes</u>	<u>Usage</u>
60	Packing Slip	Packing Slip	
61	Nutrition Cover	Dietitian	All of these are part of food records to be sent to the NCC for analysis.
62	Diet Recall	Dietitian	
63	MDRD Recipe	Dietitian	
64	3-Day Food Record	Patient	
*65	Anthropometry	Dietitian	To record measures at B2, F6 and every 4 months after.
*66	Phantom Matching	Dietitian	To identify real patient to match with QC
*71	Study Diet Prescription	Dietitian	To record Follow-Up Rx prior to discussing with patient at FU 1
*72	Special Dietary Considerations	Dietitian	Every time a FU Rx Changes this must be completed
*73	Pill Count	Anyone	To keep track of adherence to Supplements
*74	Dietary Satisfaction	Patient	To monitor degree of satisfaction with diet B0, B3, and every 4 months
*76	Summary of Counseling Plan	Dietitian	To summarize progress
*77	Patient Care Time Log	Dietitian	To keep track of time spent in various activities for the patient.
*78/78P	Nutrition History	Dietitian/ Patient	To be completed at screening to indicate history of eating patterns etc. for each patient
*79	Special Food Products Order	Dietitian	To keep track of what special foods patients seem to like.

* To be entered into Entrypoint 90

Modification of Diet in Renal Disease Study
FOLLOW UP

FORM #	BASELINE			RANDOMIZATION									FOLLOW UP																
	0	1	2	3	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
1	X																												
2		X																											
3			X																										
50			X																										
51			X																										
4				X																									
5			X	X																									
6			X	X																									
7				X																									
8				-----	X																								
9																													
13																													
16			X	X																									
17			X	X	X																								
18				X																									
19				X																									
26			X	X	X																								
27																													
28																													
29																													
46			X	X	X																								
48				X																									
65				X																									
71																													
73 (Diet K only)																													
74			X																										
76																													
77				X	X	X																							
78/78P																													
C																													
E			X	X	X																								
N			X	X	X																								
T																													
R																													
A																													
L																													
42			X																										

* 80A
+ at F1A and F2A also

FORMS COMPLETED AT CLINICAL CENTERS BY VISIT

<u>VISITS</u>	<u>FORMS</u>
Prior to Screening Visit	01
Screening	03, 29, 46, 78/78P, 50, 51 (when necessary)
B0	04, 06, 16, 17, 26, 46, 74, 77
B0A	65
B1	05, 07, 17, 26, 46, 48, 77
B2	05, 17, 18, 26, 27 (preparation), 46, 65, 77
B3	05, 06, 08, 16, 17, 19, 26, 28, 46, 52, 77
Randomization	09
F1	05, 17, 26, 46, 71, 76, 77
F1A, F2A	76
F3, F7, F9, F13, F15, F19, F21 F25, F27, F31, F33, F37, F39, F43, F45	05, 17, 26, 46, 73 ^o , 76, 77
F5, F11, F17, F23, F29, F35, F41, F47	05, 17, 18 ⁺ , 26, 27 (preparation), 46, 73 ^o , 76, 77
F2	05, 06, 16, 17, 19 [*] , 26, 46, 73 ^o , 76, 77
F6, F14, F18, F26, F30, F38, F42	05, 06, 17, 26, 46, 52, 65, 73 ^o , 74 ⁺⁺ , 76, 77
F10, F22, F34, F46	05, 06, 17, 26, 46, 48, 65, 73 ^o , 76, 77
F4, F8, F16, F20, F28, F32, F40, F44	05, 06, 16, 17, 19 ^{**} , 26, 28, 46, 73 ^o , 76, 77
F12, F24, F36, F48	05, 06, 13, 16, 17, 19 [*] , 26, 28, 29, 46 ⁻ , 52, 73 ^o , 74, 76, 77

FOOD RECORDS & 24-HOUR RECALLS NOT INCLUDED

- ++ Only at F6, not at any others
- * Diet K Only at F2, F12, and F36. All patients at F24 and F48
- ** Diet K only at F4, F20, F28 and F44. All patients at F8, F16, F32 and F40
- 2 Form 46's - one for sitting and one for standing blood pressures
- + Not at F5 or F17 or F29 or F41, only at F11 and F23 and F35 and F47
- o Diet K only
- ✓ F6, F18, F30, F42 only

Modification of Diet in Renal Disease Study
UNSCHEDULED FORMS

Form #

- 10 Unscheduled Medical Attention Form
- 11 Stop Point Form
- 12 Abbreviated Follow-up Form (stop point patients - every four months)
- 14 Multiple Missed Visits Form
- 15 Death Notification Form
- 22 QC ID Matching Form - 2 times per year per center
- 23 Action Item Response Form - Monthly for any patient who reached action item.
- 24 Out of Range Data Form
- 25 Data Change Form
- 30 Patient Transfer Form
- 31 Study C Assignment Form
- 34 Central Lab Quality Control Form - every 4 months
- 38 Safety Variable Review Form - Clinical Management Committee (CMC)
- 40 Stop Point Review Form (CMC)
- 41 Death Review Form (CMC)
- 47 Study F Form every 6 months
- 49 Compliance Committee Review Form
- 66 NCC Phantom Matching
- 72 Special Dietary Considerations
- 79 Special Food Products Order Form

Categories of Forms

A. Recruitment

1. Recruitment Form (00)
2. 800 Phone Line Log

B. Screening

1. Chart Review (01)
2. Eligible for Visit But Does not Have One (02)
3. Screening Form (03)
4. Nutrition History (78)
5. Informed Consent
6. Recruitment (50)
7. Other Evidence of Disease (51)

C. Randomization

1. Secondary Screening (08)
2. Informed Consent
3. Randomization Form (09)
4. Study A & B Randomization (37)

Categories of Forms

D. Routine Visits

1. Examination Forms (04, 05)
 - Form 4 at B0 Only
 - Form 5 Once per Month thereafter
2. Lab Forms (Mailing and Reports)
 - a. Local Lab Form (06)
 - b. Blood Pressure (46)
 - c. Anthropometry (65)
 - d. Pill Count (73)
 - e. Mailing Forms and Central Lab Reports Forms
 - i. GFR (16/42)
 - ii. 24-Hour Urine (17/32)
 - iii. Blood (17/33)
 - iv. EKG (18/35)
 - v. Amino Acids (19/36)
3. Patient Questionnaires
 - a. Patient Symptom Form (26)
 - b. Quality of Well Being (27)
 - c. Symptom Check List (28)
 - d. Leisure Time Physical Activity (48)
 - e. Dietary Satisfaction (74)
4. Other Baseline Forms (Baseline Visit 1)
 - a. Renal Diagnosis Form (07)
 - b. Economic Data (29)
5. Routine Dietary Forms
 - a. Counselling Summary (76)
 - b. Patient Care Time Log (77)
 - c. Special Food Products Order Form (79)
 - d. Food Record Forms (60-64)

Categories of Forms

E. Special Events

1. Abbreviated Follow-Up after a Stop Point (12)
2. Study F Form (47)
3. Annual Follow-Up (13)
4. Reasons for Missed Visits (14)
5. Unscheduled Attention (10)
6. Action Item Response (23)
7. Stop Point (11)
8. Death (15)
9. Study C (31)
10. Patient Transfer (30)
11. Committee Forms
 - a. Stop Point Review (40)
 - b. Death Review (41)
 - c. Safety Variable Review (38)
 - d. Compliance Committee Review (49)
12. Study Diet Prescription (71)
13. Special Dietary Considerations (72)

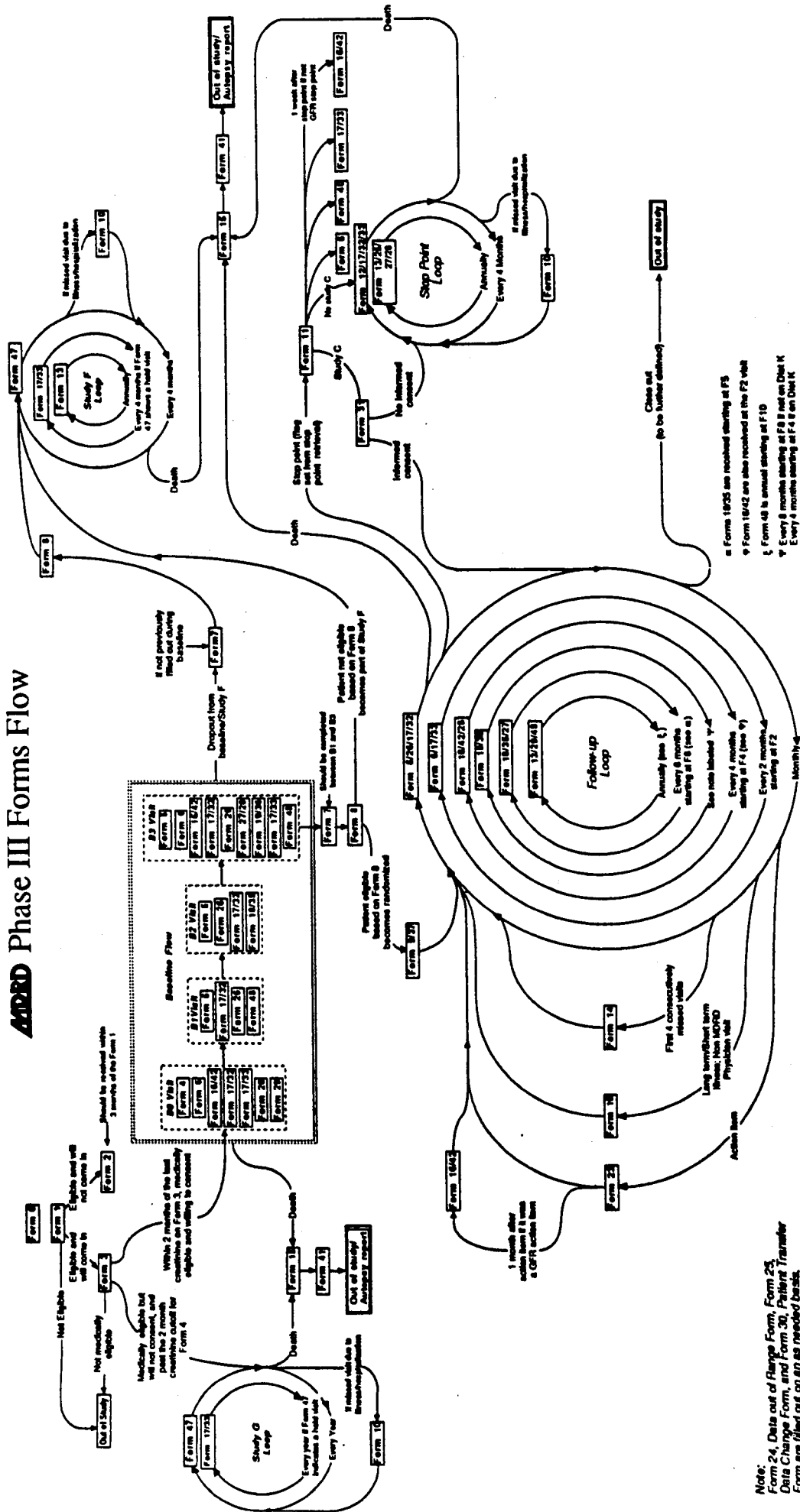
F. Quality Control

1. Central Lab QC ID Matching (22)
2. NCC Phantom Matching (66)
3. Central CAP QC (34)

G. Data Management

1. Data Out-of-Range (24)
2. Data Change (25)

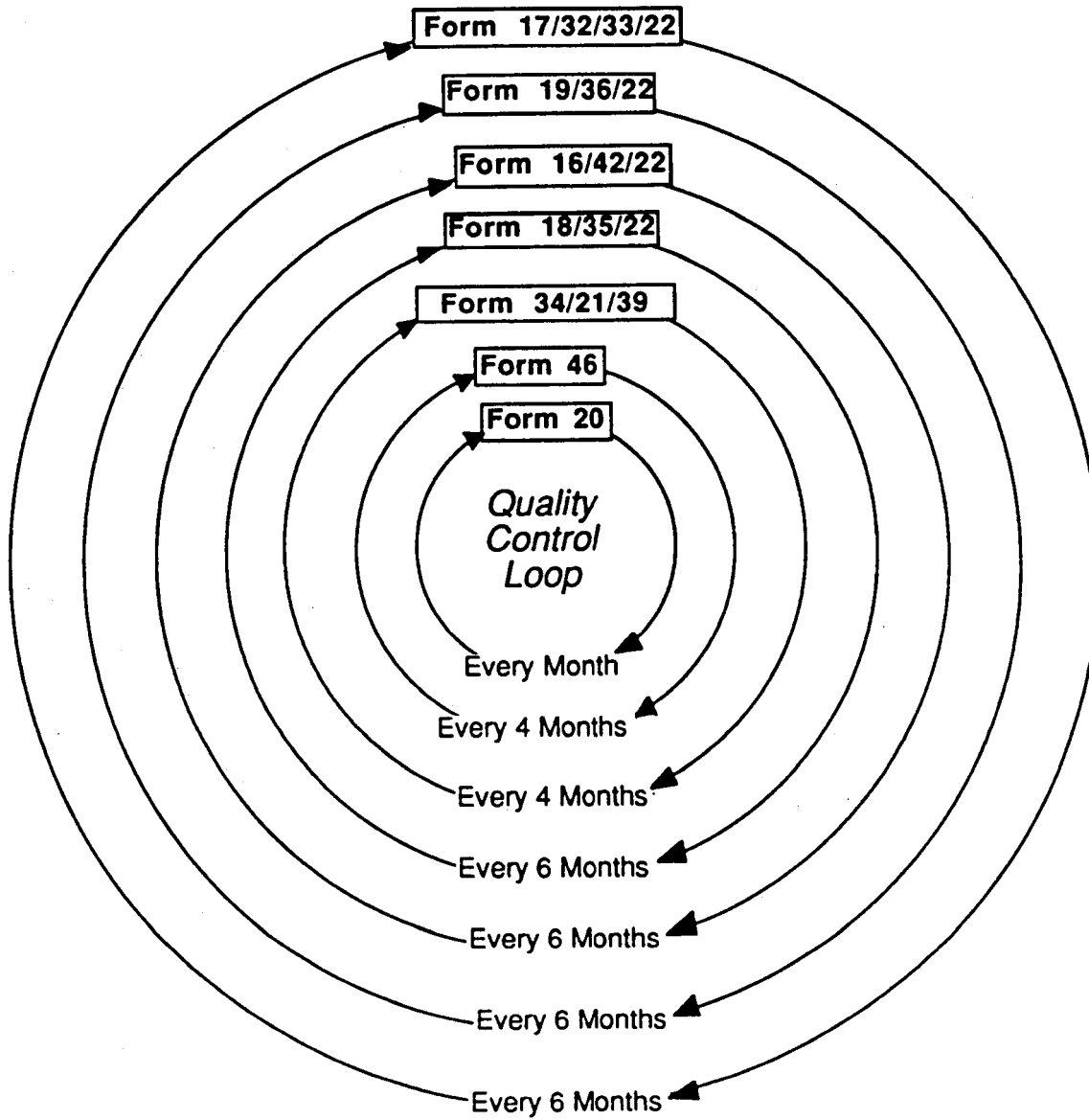
AMRD Phase III Forms Flow



Note: 24, Data out of Range Form, Form 25, Data Change Form, and Form 30, Patient Transfer Form are filled out on an as needed basis.

2.11.5

MDRD Phase III QC Forms Flow



For DCC Use Only
Rev. 4 1/20/90

Check here if Rekey Verification Forms

Page 1 of 2



**Modification of Diet in Renal Disease Study
MDRD Packing/Order Slip**

Sender Name: _____ Date Sent: ____/____/____
Clinical Center: _____

Quantity		Form Number	Form Name	For DCC Use Only
Sent	Ordered			
			Screening Informed Consent	
			Baseline Informed Consent	
			Follow-Up Informed Consent	
			GFR Informed Consent	
			QWB Informed Consent	
			Study C Informed Consent	
		#00	Clinical Center Recruitment Form	
		#01	Chart Screening Form	
		#02	Screening Visit Not Done	
		#03	Screening Form	
		#04	Demographic and Baseline Examination Form	
		#05	Monthly Examination Form	
		#06	Local Laboratory Measurement Form	
		#07	Renal Diagnosis Form	
		#08	Secondary Screening/Baseline Dropout Form	
		#09	Randomization Form (Clinical Center)	
		#10	Unscheduled Medical Attention Form	
		#11	Stop Point Form	
		#12	Abbreviated Follow-Up Form	
		#13	Annual Follow-Up Form	
		#14	Multiple Missed Visits Form	
		#15	Death Notification Form	
		#16	GFR Determination Worksheet	
		#17	Central Laboratory Mailing Form	
		#18	EKG Mailing Form	
		#19	Amino Acid Mailing Form	
		#20	Local Lab Quality Control Form	
		#21	CAP Quality Control Form	
		#22	Central Lab QC ID Matching Form	
		#23	Action Item Response Form	
		#24	Data Out of Range Form	
		#25	Data Change Form	
		#26	Symptom Form	
		#27	Quality of Well Being Form	
		#28	Sickness Check List SCL-90-R Form	
		#29	Economic Information Form	
		#30	Patient Transfer Form	
		#31	Study C Assignment Form	

**Modification of Diet in Renal Disease Study
MDRD Packing/Order Slip**

Quantity		Form Number	Form Name	For DCC Use Only
Sent	Ordered			
		#43	Close Out Form	
		#44	Close Out For Stopped, Study F & G	
		#45	Post Close Out Form	
		#46	Local Blood Pressure Form	
		#47	Studies F & G Form	
		#48	Leisure Time Physical Activity Form	
		#50	Recruitment Data for Patients in Baseline	
		#51	Other Evidence of Renal Disease Form	
		#65	Anthropometry Form	
		#66	NCC Phantom Matching Form	
		#70	Baseline Diet Prescription Form	
		#71	Study Diet Prescription Form	
		#72	Special Dietary Considerations Form	
		#73	Pill Count Form	
		#74	Dietary Satisfaction Questionnaire	
		#76	Compliance Counseling Summary Form	
		#77	Dietitian's Time Log Form	
		#78/78-P	Nutrition History Questionnaire	
		#79	Special Food Products Order Form	
		# - -	Packing / Order Slip	

MDRD

Modification of Diet in Renal Disease Study MDRD 800 Line Daily Log

1. Date..... / /

2. Initials (person receiving phone call).....

3. Person calling.....

- 1 = Patient
- 2 = Physician
- 3 = Family Member
- 4 = Other (Specify: _____)

4. a. Patient Name: _____

b. Patient Address: _____

c. Patient Telephone..... - -

5. a. Physician Name: _____

b. Physician Address: _____

c. Physician Telephone..... - -

6. Code number of center referred to (see reference list).....

7. Where did caller hear about study 800 number.....

- 1 = Relative/friend
- 2 = Personal physician
- 3 = Study brochure
- 4 = Newspaper
- 5 = Radio
- 6 = Television
- 7 = Other (Specify: _____)

2.13.2

**Modification of Diet in Renal Disease Study
CLINICAL CENTER RECRUITMENT FORM**

This form is to be completed for all initial phone contacts from potential study participants initiated through the 800 number or from outside the clinic. These phone contacts should be referred to someone at the center knowledgeable in the eligibility requirements for the MDRD Study.

If a patient contacts a center via a letter, this form should still be completed.

<u>QUESTION #</u>	<u>INSTRUCTIONS</u>
2	If you have an answering machine that takes a message from a caller on day 1 for instance, but you don't actually contact the patient until day 6. You should enter the date of day 6 when you talked with the person and got the information.
3	Note the word <u>first</u> . You may be in contact with this person after they called the 800 number, but where did the person learn of the 800 number? If the patient heard about the study from a friend who had heard about it on television, you should mark a 6 = television. If you get two or more responses to the question you should enter only one response. You should try by talking with the person to get at which place really made the patient make the phone call. If you can't do this, enter the choice which appears first on the form. (If T.V. and radio, enter 5 = radio) Do not enter "other" and specify T.V. and radio for instance.
6-10	These questions relate to eligibility. As soon as you determine the person is not eligible, you can skip to item 103. If creatinine is unknown, leave blank. If the person is eligible by these criteria, you may initiate further contact. A Form 1 must be completed if the person is considered for entrance into the study even if your first contact is a visit and not just a chart review.
11	If the person will be contacted further, (or for your own information), you may complete the Name, Address, and Phone here. You should not and cannot enter these items in Datalex.
103-104	The data recorded here should be entered at the center and transmitted as usual. It will not be connected to the MDRD database however (note no ID number of any kind). We will simply use these data to tally how people learned of the study and what percent of these people were eligible for further consideration.

2.14

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Rev. 1 10/1/88

E ___
V ___
T ___



Modification of Diet in Renal Disease Study Clinical Center Recruitment Form

This form is to be completed for each initial phone contact with a potential study participant.

FORM # 00

1. Clinical Center
 2. Date of Contact..... / /
 3. Where did the person first hear about the study.....
 - 1 = Relative/Friend
 - 2 = Personal Physician
 - 3 = Study Brochure
 - 4 = Newspaper (Specify: _____)
 - 5 = Radio (Specify: _____)
 - 6 = TV (Specify: _____)
 - 7 = Other (Specify: _____)
 4. Did person call 800 number prior to being in contact with center? (1 = yes, 2 = no)
 5. Sex (1 = Male, 2 = Female).....
- Items 6-10 relate to eligibility. When you determine that a person is not eligible, you do not have to complete the other items.
6. Age (18 to 70 to be eligible).....
 7. Has person gone on dialysis? (1 = yes, 2 = no)
 8. Is person a kidney transplant recipient? (1 = yes, 2 = no)
 9. Does person take insulin? (1 = yes, 2 = no)
 10. Serum creatinine (mg/dl) (1.2 - 7.0 female, 1.4 - 7.0 male to be eligible)
 11. Name _____
Address _____

 - Phone Number - - - - -
 103. Date form entered..... / /
 104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

**Modification of Diet in Renal Disease Study
CHART SCREENING FORM**

This form is to be used to assist in the chart review, screening process. It should be completed on all patients meeting creatinine, age, diabetes and kidney recipient criteria.

<u>ITEM</u>	<u>INSTRUCTIONS</u>
1. ID Code	The ID code will be assigned sequentially for each center. The first two digits are for the clinical center.
2. Name Code	The name code should consist of the first two letters of the patient's first name and the first two letters of the patient's last name. Example: MARY JONES = MAJO Within each center you should have unique namecodes. Do not allow more than one patient to have the same code. Use a different letter if the situation arises.
3. Clinical Center	Enter the permanent code number for your center as follows: 01 = Bowman Gray School of Medicine 02 = Brigham and Women's Hospital/ Beth Israel Hospital 03 = Brookdale Hospital Medical Center 04 = Duke University School of Medicine 05 = Emory University 06 = George Washington University Medical Center 07 = Harbor Medical Center 08 = New England Medical Center Hospital/ Massachusetts General Hospital 09 = Ohio State University Hospitals 10 = University of Florida 11 = University of Iowa Hospital and Clinics 12 = University of Miami Jackson Memorial Medical Center 13 = University of Southern California 14 = University of Texas Health Science Center 15 = Vanderbilt University Medical Center
5.a.	Enter a 1 = yes if the patient was found during a systematic review of records or laboratory results at a location where your center has tried to go through each record or result and complete a form for each. Enter a 2 = no if the patient was self referred, individually referred by a physician, or referred to you in a group of likely eligible patients.

**Modification of Diet in Renal Disease Study
CHART SCREENING FORM**

QUESTION #

INSTRUCTIONS

5b. If the patient finds you through publicity 7 = self referred. If the answer to 5b is 6 or 7 then you may skip to item 8 and leave items 6 and 7 blank. Both questions 5a and 5b should be completed.

7a-d. For parts 'a' - 'd', if there is documented evidence that the patient has the specified renal disorder, enter a 1 in the appropriate space.

7e. Note, the following are serious medical conditions for which a patient must be excluded from further study.

HYPERTENSION

Enter a 1 if the patient has had a diastolic blood pressure greater than 95 millimeters of mercury or a systolic blood pressure greater than 180 millimeters of mercury on the most recent measurement in the past three months despite Maximal medical therapy.

CANCER

Enter a 1 if the patient has had metastatic cancer or resection of a primary malignant lesion within the past year (except squamous cell or basal cell carcinoma of the skin). Also, enter a 1 for patients who are undergoing current adjuvant chemotherapy, or for patients who have multiple myeloma or renal disease due to a monoclonal gammopathy.

HEART

The New York Heart Association functional classes are as follows:

- Class 1: No symptoms.
- Class 2: Comfortable at rest. Symptoms with ordinary physical activity.
- Class 3: Comfortable at rest. Symptoms with less than ordinary physical activity.
- Class 4: Symptoms at rest. If the patient displays disability from heart failure (\geq Class 3) despite therapy with digitalis, diuretics, and afterload reducing agents, enter a 1.

LUNG

Enter a 1 if the patient demonstrates severe chronic lung disease causing cor pulmonale or requiring steroid therapy.

LIVER

If two of the patient's serum bilirubin measurements within the past three months are greater than 1.5 mg/dl, enter a 1.

OR

If there is evidence of portal hypertension (with or without a known diagnosis of cirrhosis) complicated by edema, enter a 1.

**Modification of Diet in Renal Disease Study
CHART SCREENING FORM**

QUESTION #

INSTRUCTIONS

OR

If two of the patients SGOTs or other serum transaminases in the past three months have been greater than 100 IU/L, enter a 1.

GI SYMPTOMS

Enter a 1 if the patient has any disease requiring treatment with diets which would seriously complicate a low protein diet prescription.

INFECTIONS

Enter a 1 if the patient has experienced chronic infections requiring prolonged antibiotic therapy within the past six months (i.e., systemic mycoses, AIDS, or active tuberculosis). This does not include uncomplicated urinary tract infections.

**COLLAGEN
VASCULAR
DISEASE**

Enter a 1 if the patient has a collagen vascular disease such as SLE or vasculitis. Patients with rheumatoid arthritis are not excluded.

**HOSPITALI-
ZATION**

If the patient has been hospitalized more than three times in the past year, or if the patient has been in the hospital for more than 60 days in the past year, enter a 1.

DISABILITY

If the patient is disabled as shown by an inability to perform most activities of daily living (such as dressing, feeding or using a toilet), enter a 1.

7f. **MEDICATIONS**

If the patient is taking any of the listed medications as therapy for their primary renal disease, enter a 1.

If the patient is taking immunosuppressive agents, enter a 1.

OR

If the patient has taken corticosteroids in excess of 7 milligrams prednisone equivalents daily for two or more months out of the past year, enter a 1.

Equivalency

Cortisol	30 mg	7.5 mg
Cortisone	37.5 mg	7.5 mg
Dexamethadone	1.125 mg	7.5 mg
Triamcinolone	6 mg	7.5 mg
Prednisolone	7.5 mg	7.5 mg
Methylprednisolone	6 mg	7.5 mg

Modification of Diet in Renal Disease
CHART SCREENING FORM

QUESTION

INSTRUCTIONS

OR

If the patient has taken gold within the past month, enter a 1.

OR

If the patient has taken penicillamine within the past month, enter a 1.

OR

If the patient has been taking more than 20 tablets of 325 mg salicylates per week, enter a 1.

OR

If the patient has taken other non-steroidal anti-inflammatory agents within the past two months, enter a 1.

OR

If the patient is taking any investigational new drugs, enter a 1. If the patient is taking Erythropoietin, enter a 1. Unless at some point the FDA approves its use for non dialysis patients. Then it will no longer be an exclusion.

- 7g. If compliance is doubtful for any reason enter a 1. Refer to Form 3, Question 12 a-m for details.
- 7h. Enter a 1 if the patient is currently enrolled in another study in which diet or drug therapy is stipulated.
- 7i. If the patient is known to be a lactating mother or pregnant, enter a 1.
- 7j. If the patient has urinary retention identified by history, physical or radiologic examination, enter a 1.
- 7k. If the patient has exhibited a previous allergic reaction following an iohalamate injection or an iodide ion, enter a 1 in the appropriate space.
9. Identify any causes for not continuing patient contact for entry into the study which at this point in time do not constitute an actual exclusion.
10. REENTRY
If a patient is screened, enters baseline, drops and then gets rescreened to enter the process again, he or she should be given a new ID code. In this instance, enter 1 = yes and the previously assigned ID code.

If a patient is simply screened a 2nd time, never having been in Baseline, a new ID should not be assigned. Complete a 2nd Form 3 labelling as S2.0 and do not complete this Form 1.

Modification of Diet in Renal Disease Study

SCREENING FORM

<u>QUESTION #</u>	<u>INSTRUCTIONS</u>
101. Date this form completed	Enter the date that the entire form is completed. Right justify.
102. Certification number	Enter your unique certification number. You thus take responsibility, for the accuracy of the data contained in this form.
103. Date form entered	Enter the date that the contents of this form have been entered into the computer. This should be the same date as when the form was completed, or as soon as possible thereafter.
104. Certification number	The data entry person's certification number must be entered. He or she thus takes responsibility for the accuracy of the entered data.



Modification of Diet in Renal Disease Study Chart Screening Form

This form is to be completed on patients considered for entry into the study, who meet the following criteria: with chronic renal disease, age 18 to 70 years, serum creatinine within the past year between 1.2 and 7.0 mg/dl for females, and between 1.4 and 7.0 mg/dl for males, not taking insulin and not a kidney transplant recipient.

FORM # 0 1

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. Sex (1 = Male, 2 = Female).....
5. a. Was this patient found during a systematic review of the records or laboratory results from a defined population? (1 = yes, 2 = no).....
- b. Source of Referral.....

1 = Nephrology clinic	5 = Laboratory
2 = Private nephrology office	6 = Specifically referred by physician
3 = Other physician's office	7 = Self referred
4 = HMO	8 = Other (20 characters maximum)
	(.....)

If 6 or 7 skip to Item 8.

6. Primary Renal Diagnoses (Code 1 to 24 as shown below).....

1 = Polycystic kidney disease	15 = Membranoproliferative glomerulonephritis
2 = Hereditary nephritis	16 = Mesangial proliferative glomerulonephritis
3 = Analgesic nephropathy	17 = Chronic renal failure with proteinuria
4 = Pyelonephritis	18 = Nephrotic syndrome without biopsy
5 = Other interstitial nephritis	19 = Absence of one kidney
6 = Obstructive uropathy - acquired	20 = IgA nephropathy
7 = Obstructive uropathy - congenital	21 = Other glomerulonephritis
8 = Vesico-ureteral reflux	22 = Other (20 characters maximum)
9 = Urinary tract stones	(.....)
10 = Hypertensive nephrosclerosis	23 = Unknown
11 = Diabetic nephropathy	24 = None
12 = Renal artery stenosis	
13 = Membranous nephropathy	
14 = Focal sclerosis	

7. Review the following exclusion criteria. Enter a 1 for any items where evidence of the exclusion is found in the chart. As soon as one of the items is marked yes, others need not be reviewed. However, if an item is reviewed in the chart and not found, enter a 2 for no.
 - a. Urinary tract - Obstruction
 - b. Renal Artery Stenosis as cause of renal insufficiency.....
 - c. Staghorn Calculi

**Modification of Diet in Renal Disease Study
Chart Screening Form**

7. (Continued)
- d. Cystinuria.....
 - e. A Serious Medical Condition (see instructions).....
 - f. Drugs (see instructions).....
 - g. Compliance to study is doubtful (see instructions).....
 - h. Currently enrolled in another diet or drug therapy study.....
 - i. Pregnant or lactating.....
 - j. Urinary retention.....
 - k. Known allergy to iodine or iothalamate.....
8. Is the patient eligible for a screening visit? (1 = yes, 2 = no).....
- If yes, the patient should be invited for a screening visit. If the patient does not come for a visit, complete Form 2. If the patient does come for a screening visit, complete Form 3.**
9. Has something else stopped the study team from pursuing the patient further?.....
- 1 = Urine protein repeatedly ≥ 10 g/day
 - 2 = Serum albumin < 3.0 g/dl
 - 3 = Body Weight
 - 4 = Other _____)
 - 5 = None
10. a. Has the patient previously been in Baseline? (1 = yes, 2 = no).....
(New ID's only assigned when this is yes)
- b. What was the previous ID Code assigned?.....
101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Date form entered..... / /
104. Certification number of data entry person

Modification of Diet in Renal Disease Study
PATIENTS ELIGIBLE FOR SCREENING VISIT
BUT WHO DO NOT HAVE ONE

Complete this form for each patient eligible for a screening visit who does not have one.

<u>QUESTION #</u>	<u>INSTRUCTIONS</u>
1. ID Code	This is the same numerical number given to the patient when screened. See Form #01.
2. Name Code	The name code consists of the first two letters of the patient's first name and the first two letters of the patient's last name as used on Form #01.
3. Clinical Center	Enter the permanent code number given to your Center.
4. Reason	Give the primary or first reason for the patient not coming in for a visit.
5. Comment	If the reason is 'other', specify in the comment area. This will not be key entered.
101. Date this form completed	Enter the date that the form is completed. Right justify.
102. Certification number of person filling out this form	Enter your unique certification number. You thus take responsibility, for the accuracy of the data contained in this form.
103. Date form entered	Enter the date that the contents of this form have been entered into the computer. This should be the same date as when the form was completed, or as soon as possible thereafter.
104. Certification number of data entry person	The data entry person's certification number must be entered. He or she thus takes responsibility for the accuracy of the entered data.

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E ___
V ___
T ___

Form # 02
Page 1 of 1



**Modification of Diet in Renal Disease Study
Patients Eligible for Screening Visit
But Who Do Not Have One**

This form is to be completed for each patient who is eligible for a screening visit, but did not have one.

FORM # 0 2

- 1. Patient Identification Number.....
- 2. Patient Name code
- 3. Clinical Center
- 4. Reason Screening Visit not held.....
 - 1 = Patient moved
 - 2 = Patient died
 - 3 = Patient on dialysis
 - 4 = Patient couldn't be reached
 - 5 = Patient refused
 - 6 = Study Team Preference
 - 7 = Other

5. Comments:

- 101. Date this form completed..... / /
- 102. Certification number of person filling out this form
- 103. Date form entered..... / /
- 104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
SCREENING FORM

Complete this form for all patients with chronic renal disease, age 18 to 70, with serum creatinine within the past year between 1.2 and 7.0 mg/dl for females, and between 1.4 and 7.0 mg/dl for males, not taking insulin and not a transplant recipient who have a visit. The form should be completed by the Study Coordinator at the conclusion of the screening visit.

QUESTION # INSTRUCTIONS

1. Enter the Patient ID Code assigned to this patient on Form #01.
2. Enter the patient's Name Code. The first 2 letters of the patient's first name and the first 2 letters of the patient's last name.
3. Enter the code associated with the Clinical Center where this patient is being evaluated. The following is a list of permanent identification codes for each Center taking part in this study.
 - 01 = Bowman Gray School of Medicine
 - 02 = Brigham and Women's Hospital/Beth Israel Hospital
 - 03 = Brookdale Hospital Medical Center
 - 04 = Duke University School of Medicine
 - 05 = Emory University
 - 06 = George Washington University Medical Center
 - 07 = Harbor Medical Center
 - 08 = New England Medical Center Hospital/
Massachusetts General Hospital
 - 09 = Ohio State University Hospitals
 - 10 = University of Florida
 - 11 = University of Iowa Hospital and Clinics
 - 12 = University of Miami Jackson Memorial Medical Center
 - 13 = University of Southern California
 - 14 = University of Texas Health Science Center
 - 15 = Vanderbilt University Medical Center
- 4c. The first Screening visit should be labelled 01.0. If patient is screened a second time enter 02.0.
6. Items 13-16 are diagnoses made by renal biopsy. Remember if "other" is specified, up to 20 digits of the specification may be entered.
7. The patient's age is calculated by subtracting the birth date from the date the form is completed.
10. If the patient is male, enter a 2. If the patient is female, refer to the most recent data recorded in the chart. If she is known to be a lactating mother or pregnant, enter a 1. If she is planning to be pregnant within 2 to 4 years, enter a 1. If not, enter a 2.

**Modification of Diet in Renal Disease Study
SCREENING FORM**

QUESTION #**INSTRUCTIONS**

11. Enter a 1 if the patient is currently enrolled in another study in which diet or drug therapy is stipulated. Enter a 2 if there is no evidence of this.
12. Final judgment regarding compliance is made by the local Principal Investigator after consultation with the patient's physician. Enter a 1 if any of the items listed is yes. Enter a 2 if not.
- a. If there is documented evidence of chronic use of heroin, cocaine, barbiturates or other illicit drugs, enter a 1. If no evidence is found, enter a 2.
 - b. If the patient's records indicate previous hospitalizations for alcoholism or previous history of arrests for alcohol abuse and there is no demonstration of cessation for the past year, enter a 1. If there is no evidence of abuse or the patient has demonstrated cessation of abuse for at least one year, enter a 2.
 - c. If there is documented evidence of a history of major psychiatric illness or psychosis requiring hospitalization or treatment by either a psychiatrist or psychotropic drugs within the past year, enter a 1. If no such evidence is apparent, enter a 2.
 - d. If the patient is illiterate, unable to understand study procedures, enter a 1. Otherwise, enter a 2.
 - e. If the patient does not appear to be motivated to participate in the study, enter a 1. Otherwise, enter a 2.
 - f. If the patient has diet preferences which will not allow compliance to study diets, enter a 1. Otherwise, enter a 2.
 - g. If the patient plans to move from the area in the next two years, enter a 1. Otherwise, enter a 2.
 - h. If the patient has no cooking facilities, or if the person responsible for the patient's cooking refuses to cooperate, enter a 1. Otherwise, enter a 2.
 - i. If the patient appears to fail to keep at least half of his or her scheduled appointments as ascertained from previous records, enter a 1. If no such evidence is found, enter a 2.
 - j. If the patient cannot communicate with study personnel, is unable to write food records, cannot read or is illiterate, enter a 1. Otherwise, enter a 2.
 - k. If the patient does not have access to a telephone at which he or she can be reached, enter a 1. Otherwise, enter a 2.

Modification of Diet in Renal Disease Study
SCREENING FORMQUESTIONINSTRUCTIONS

12. 1. If the patient exhibits some characteristics which make you feel his or her compliance is doubtful, (i.e., patient refusal) enter a 1. Write in the evidence in the space provided. Otherwise, enter a 2.
- m. If compliance is doubtful for some other reason, enter a 1 here and specify reason.
- If any part of item 12 is yes, the patient is not eligible. However, continue to complete the remainder of the form.
13. For parts 'a' - 'd', if there is documented evidence that the patient has the specified renal disorder, enter a 1 in the appropriate space. If no evidence is found, enter a 2.
14. If the patient has urinary retention identified by history, physical or radiologic examination, enter a 1. Otherwise, enter a 2.
15. a. Enter a 1 if the patient has had metastatic cancer or resection of a primary malignant lesion within the past year (except squamous cell or basal cell carcinoma of the skin). Also, enter a 1 for patients who are undergoing current adjuvant chemotherapy, or for patients who have multiple myeloma or renal disease due to a monoclonal gammopathy. If none of these are documented, enter a 2.
- b. The New York Heart Association functional classes are as follows:
- Class 1: No symptoms.
 - Class 2: Comfortable at rest. Symptoms with ordinary physical activity.
 - Class 3: Comfortable at rest. Symptoms with less than ordinary physical activity.
 - Class 4: Symptoms at rest.
- If the patient displays disability from heart failure (\geq Class 3) despite therapy with digitalis, diuretics, and afterload reducing agents, enter a 1. If no such evidence is found, enter a 2.
- c. Enter a 1 if the patient demonstrates severe chronic lung disease causing cor pulmonale or requiring steroid therapy. If no such evidence is found, enter a 2.

Modification of Diet in Renal Disease Study
SCREENING FORMQUESTION #INSTRUCTIONS

15.

d. If two of the patient's serum bilirubin measurements within the past three months are greater than 1.5 mg/dl, enter a 1. If not, or if the patient has Gilbert's disease, enter a 2. If there is evidence of portal hypertension (with or without a known diagnosis of cirrhosis) complicated by edema, enter a 1.

If two of the patients SGOTs or other serum transaminases in the past three months have been greater than 100 IU/L, enter a 1. If no such evidence is found or the patient has intermittent asymptomatic elevated transaminases, enter a 2.

e. Enter a 1 if the patient has any disease requiring treatment with diets which would seriously complicate a low protein diet prescription. If no such evidence is found, enter a 2.

f. Enter a 1 if the patient has experienced chronic infections requiring prolonged antibiotic therapy within the past six months (i.e., systemic mycoses, AIDS, or active tuberculosis). This does not include uncomplicated urinary tract infections. If no such illnesses have occurred, enter a 2.

g. Enter a 1 if the patient has a collagen vascular disease such as SLE or vasculitis. Patients with rheumatoid arthritis are not excluded; for these patients, enter a 2. Enter a 2 if none of these diseases are evident.

h. If the patient has been hospitalized more than three times in the past year, enter a 1. If not, enter a 2.

i. If the patient has been in the hospital for more than 60 days in the past year, enter a 1. Otherwise, enter a 2.

j. If the patient is disabled as shown by an inability to perform most activities of daily living (such as dressing, feeding or using a toilet), enter a 1. If not, enter a 2.

16.

If the patient is taking any of the listed medications, enter a 1. Otherwise, enter a 2.

a. If the patient is taking immunosuppressive agents, enter a 1. Otherwise, enter a 2.

**Modification of Diet in Renal Disease Study
SCREENING FORM**

QUESTION # INSTRUCTIONS

- b. If the patient has taken corticosteroids in excess of 7 milligrams prednisone equivalents daily for two or more months out of the past year, enter a 1. If no evidence of this is found, enter a 2.

	<u>Equivalency</u>	
Cortisol	30 mg	7.5 mg
Cortisone	37.5 mg	7.5 mg
Dexamethasone	1.125 mg	7.5 mg
Triamcinolone	6 mg	7.5 mg
Prednisolone	7.5 mg	7.5 mg
Methylprednisolone	6 mg	7.5 mg

- c. If the patient has taken gold within the past month, enter a 1. If no evidence of this is found, enter a 2.
- d. If the patient has taken penicillamine within the past month, enter a 1. If no evidence of this is found, enter a 2.
- e. If the patient has been taking more than 20 tablets of 325 mg salicylates per week, enter a 1. If no evidence of this is found, enter a 2.
- f. If the patient has taken more than the MDRD Maximum Allowable dose of other non-steroidal anti-inflammatory agents within the past two months, enter a 1. If no evidence of this is found, enter a 2. See the attached equivalency chart for maximum allowable dose.
- g. If the patient is taking any investigational new drugs, excluding Erythropoietin enter a 1. If no evidence of this is found, enter a 2.
- h. Until further notice from the FDA, use of Erythropoietin is an exclusion.
17. If the patient has exhibited a previous allergic reaction following an iohalamate injection or an iodide ion, enter a 1 in the appropriate space. If not, enter a 2.
18. a. Enter the date on which the most recent serum albumin was determined. This date must be within the past three months.
- b. Enter the most recent serum albumin value found. The value should be recorded in grams per deciliter, rounded to the nearest tenth, right justified, and zero-filled. If the patient is eligible this must be completed. If the patient is not eligible this may be left blank.

MAXIMUM ALLOWABLE DOSE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

<u>PRODUCT NAME</u>	<u>ADWIL</u>	<u>IBUBROFEN</u>	<u>MOJIN</u>	<u>NUBRIN</u>	<u>RUFIN</u>
Pharmaceutical Firm	Whitehall	Danbury	Upjohn	Bristol	Boots
Active Ingredient	Ibuprofen	Ibuprofen	Ibuprofen	Ibuprofen	Ibuprofen
Tablet Strength	200 mg	400 mg 600 mg	400 mg 600 mg 800 mg	200 mg	400 mg 600 mg
Recommended Dosage	1 tablet q 4-6 h		usual dose: 1200-3200 mg per day Not to exceed 3200 mg per day	Not to exceed 6 tablets unless directed by a physician	Not to exceed 2400 mg per day
Maximum allowable weekly dose based on MDRD study protocol	6-200 mg tablets	3-400 mg tablets 2-600 mg tablets	3-400 mg tablets 2-600 mg tablets	6-200 mg tablets	3-400 mg tablets 2-600 mg tablets

MAXIMUM ALLOWABLE DOSE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

<u>PRODUCT NAME</u>	<u>ANAPROX</u>	<u>CLINORIL</u>	<u>DOLOBID</u>	<u>FELDENE</u>	<u>INDOCIN</u>
Generic Name	Naproxen Na	Sulindac	Diflunisal	Piroxicam	Indomethacin
Tablet Strength	275 mg	150 mg 200 mg	250 mg 500 mg	10 mg 20 mg	25 mg 50 mg 75 mg (Indocin SR) Suppositories available
Recommended Dosage	Max. dosage 1375 mg daily	2 tablets daily with food (400 mg max. daily)	1000 mg initially 500 mg q 12o	20 mg (single daily dose)	max. 100 mg/day
Max. allowable weekly dose based on MDRD study protocol	825 mg (3 tablets)	300 mg (2-150 mg tab)	750 mg (3-250 mg tabs)	15 mg (1-20 mg tabs)	75 mg (3-25 mg tabs)

MAXIMUM ALLOWABLE DOSE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

<u>PRODUCT NAME</u>	<u>NECLOMEN</u>	<u>NAPROSYN</u>	<u>NALFON</u>	<u>PONSIVEL</u>	<u>TOLECTIN</u>
Generic Name	Meclofenamate	Naproxen	Fenoprofen	Mefenamic acid	Tolmelin Na
Tablet Strength	50 mg	250 mg 375 mg 500 mg	200 mg 300 mg 600 mg	250 mg	200 mg 400 mg
Recommended Dosage 240);	200-400 mg/day admin in 3-4	250 mg 375 mg	200 mg q 4-60 (Analgesic)	500 mg initially 250 mg q 60	400 mg initially tid (1200 mg max. in
	equal	doses	max.	mg	300-600
daily	of 400 mg/day	max. 1250 mg/day	Rheu Arth	then 600-1800 mg	
doses/day		3-4 x	daily	divided in 3	except 4 doses/day can be given for
Rheu			Arth		
Maximum allowable weekly dose based on MDRD study protocol	300 mg (6 tablets)	375-562 mg tablets	900-1800 mg tablets	938 mg = 4 tablets	900 mg (5-200 mg tablets) 1350 mg (4-400 mg tablets)

Modification of Diet in Renal Disease Study
SCREENING FORMQUESTION # INSTRUCTIONS

- c. Enter a 1 if the value in part 'b' is less than 3.0 g/dl. If the serum albumin is greater than or equal to 3.0 g/dl, enter a 2.
19. Standard Body Weight should be completed by the dietitian. Instructions for its completion are included in the Nutrition portion of the Manual of Operations. If the patient is not eligible, this section may be left blank.
- a. The patient's height should be recorded in centimeters, rounded to the nearest tenth of a centimeter. Only values between 120 and 200 may be entered. Height should be measured twice, both should be recorded and the average used for further calculations. For more specific instructions see the Nutrition portion of the Manual of Operations.
- b. The right elbow breadth should be recorded in centimeters rounded to the nearest tenth.
- c. The patient's frame size is determined from his or her elbow breadth.
- d. The patient's actual body weight should be entered in kilograms, rounded to the nearest tenth. The weight should be measured twice and the average used. Refer to the Nutrition portion of the Manual of Operations for further instructions. The dietician does not have to be the person to complete this item.
- e. The standard weight is determined according to height, sex, and frame size.
- f. (average from part 'd'/answer to part 'e') multiplied by 100. The value should be rounded to a whole percentage point, then right justified.
- g. If the value in part 'f' is greater than or equal to 80% and less than or equal to 160%, then enter a 2. If it is outside this range, enter a 1. The patient is not eligible.
- h. Enter dietitian's certification number.

**Modification of Diet in Renal Disease Study
SCREENING FORM**

QUESTION # INSTRUCTIONS

20. To be eligible: items 8-17 and 18c must be no, item 19g must be no, MAP must be ≤ 125 and the first creatinine value must be within range (or Form 51 indicates other evidence of renal disease) and within the past month. If item 20 indicates not eligible - DO NOT HOLD A BASELINE VISIT.
21. If the patient is willing and able to give consent, enter a 1. If not, enter a 2.
101. Enter the date that the form is completed. Right justify.
102. Enter your unique certification number. You thus take responsibility, for the accuracy of the data contained in this form.
103. Enter the date when the form was entered into the computer. This should be the same date that the form was completed, or as soon as possible thereafter.
104. The data entry person's certification number must be entered. He or she thus takes responsibility for the accuracy of the entered data.

In completing the creatinine chart be sure the most recent value is first for eligibility determination. If a patient is REscreened, enter only additional creatinine values since the first completion of this form. If there are no new values, repeat the most recent one in the first space provided.

It is very important to get the past creatinine measurements from the patient's chart. This may involve writing to the patient's physician in another city to obtain data.

If two creatinines are reported in the chart on the same day, an average value should be entered on the form.

If creatinines are available during hospitalizations they should be included on page 6. Do not make judgments regarding which values to enter and which not to. Include ALL creatinine values available.

Form 51/
Creatinines

If the patient's creatinine is too low but there is other evidence of renal disease (thus making the patient eligible) you must complete Form 51.

If the only thing making a patient ineligible is that the creatinine is too low and there is not other evidence of renal disease do the following:

item 12 = Yes

item 12 m = 1 = Yes

item 12 m = NO OTHER EVIDENCE , OR CREATININE IS TOO LOW

item 20 = 2 = No

MDRD

Modification of Diet in Renal Disease Study Screening Form

This form is to be completed at the conclusion of the screening visit on all patients with chronic renal disease, age 18 to 70 years, serum creatinine within the past year between 1.2 and 7.0 mg/dl for females, and between 1.4 and 7.0 mg/dl for males, not taking insulin and not a kidney transplant recipient. For those patients who are eligible, the Baseline Visit 0 must take place within two months of the date of the serum creatinine which determines eligibility.

FORM # 03

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of Screening Visit..... / /
b. Visit Type..... S
c. Visit Number.....
5. Sex (1 = male, 2 = female).....
6. Primary Renal Diagnosis.....

1 = Polycystic kidney disease	15 = Membranoproliferative glomerulonephritis
2 = Hereditary nephritis	16 = Mesangial proliferative glomerulonephritis
3 = Analgesic nephropathy	17 = Chronic renal failure with proteinuria
4 = Pyelonephritis	18 = Nephrotic syndrome without biopsy
5 = Other interstitial nephritis	19 = Absence of one kidney
6 = Obstructive uropathy - acquired	20 = IgA nephropathy
7 = Obstructive uropathy - congenital	21 = Other glomerulonephritis
8 = Vesico-ureteral reflux	22 = Other (20 characters maximum)
9 = Urinary tract stones	(.....)
10 = Hypertensive nephrosclerosis	23 = Unknown
11 = Diabetic nephropathy	24 = None
12 = Renal artery stenosis	
13 = Membranous nephropathy	
14 = Focal sclerosis	

ELIGIBILITY DETERMINATION

7. Patient's age.....
8. Is the patient taking insulin? (1 = yes, 2 = no).....
9. Is the patient a kidney transplant recipient? (1 = yes, 2 = no).....
10. Is the patient pregnant or lactating? (1 = yes, 2 = no).....

Modification of Diet in Renal Disease Study Screening Form

11. Is the patient currently enrolled in another study in which diet or drug therapy is stipulated? (1 = yes, 2 = no) _____

12. Is compliance doubtful for one or more of the following reasons? (1 = yes, 2 = no) _____

If yes, (for items a through m, code 1 = yes, 2 = no)

a. drug abuse?.....

b. alcohol abuse?.....

c. major psychiatric illness (within past year)?.....

d. poor understanding of study?.....

e. limited motivation?.....

f. unsuitable diet preferences?.....

g. transient residence?.....

h. unsuitable home environment?.....

i. pattern of frequently missed clinic appointments?.....

j. cannot communicate well?.....

k. lack of access to a telephone?.....

l. poor compliance in other clinical trials?.....

m. other (20 characters maximum)(.....)

13. Does the patient have any of the following known and documented renal disorders? (1 = yes, 2 = no) _____

If yes, (for items a through d, code 1 = yes, 2 = no)

a. urinary tract obstruction.....

b. renal artery stenosis as the cause of renal insufficiency.....

c. branched or staghorn calculi.....

d. cystinuria.....

14. Does the patient have documented or known evidence of urinary retention? (1 = yes, 2 = no).....

**Modification of Diet In Renal Disease Study
Screening Form**

15. Does the patient have any of the following known and documented chronic serious medical conditions? (1 = yes, 2 = no)

If yes, (for items a through j, code 1 = yes, 2 = no)

- a. malignancy (within the past year - exclude skin)
- b. heart disease NYHA class 3 or 4?
- c. severe chronic lung disease
- d. clinically significant liver disease
- e. gastrointestinal disease (which affects diet or nutrition).....
- f. chronic systemic infections (within past six months).....
- g. collagen vascular disease (except for rheumatoid arthritis).....
- h. Has the patient been hospitalized more than three times in the past year?
- i. Has the patient been in hospital more than 60 days within the past year?
- j. Is the patient disabled?.....

16. Is the patient taking any of the following medications? (1 = yes, 2 = no)

If yes (for items a through h, code 1 = yes, 2 = no)

- a. immunosuppressive agents
- b. corticosteroids.....
- c. gold (within past month)
- d. penicillamine (within past month).....
- e. salicylates.....
- f. other non-steroidal anti-inflammatory agents.....
- g. investigational new drugs (excluding Erythropoietin).....
- h. Erythropoietin

17. Does the patient have a known allergy or adverse reaction to iodine or iothalamate? (1 = yes, 2 = no).....

Modification of Diet in Renal Disease Study Screening Form

18. Serum albumin
- a. Date of most recent serum albumin
(must be within the past three months)..... ____/____/____
 - b. Most recent serum albumin (g/dl) ____ . ____
 - c. Is most recent value less than 3.0 g/dl? (1 = yes, 2 = no)..... ____

NOTE: If any of the answers to questions 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, or 18c is yes, the patient is not eligible. Item 19 does NOT need to be completed. Skip to Item 20.

If eligible thus far complete Items 19 onward.

FOR ALL PATIENTS, COMPLETE THE CHART OF CREATININE VALUES AND DATES ON PAGE 5.

19. Standard Body Weight (to be provided by dietitian)
- a. height (cm) 1.)..... ____ . ____
2.)..... ____ . ____
 - b. elbow width (cm) 1.)..... ____ . ____
2.)..... ____ . ____
 - c. frame size..... ____
1 = Small
2 = Medium
3 = Large
 - d. body weight (kg) 1.)..... ____ . ____
2.)..... ____ . ____
 - e. standard weight (kg)..... ____ . ____
 - f. percentage of standard weight (%)..... ____ . ____
 - g. Is the percentage of standard weight outside the allowable range
(80% -160%)? (1 = yes, 2 = no)..... ____
 - h. certification number of dietitian ____ . ____

**Complete Form 46 to record Patient Blood Pressure.
MAP must be ≤ 125 for patient to be eligible.**

20. Does the patient meet ALL eligibility requirements? (Items 8 - 17, 18c are no, 19g = no, MAP ≤ 125 from Blood Pressure Form and 1st Creatinine within range) (1 = yes, 2 = no)..... ____
21. Is the patient willing and able to give consent? (1 = yes, 2 = no) ____

The patient is eligible to enter Baseline if Items 20 and 21 are both yes.

Be sure the patient has signed the Primary (Baseline) Informed Consent, and schedule the Baseline Visit 0 within two months.

If the patient is eligible, but will not consent to enter baseline (Item 20 = yes and 21 = no), the patient is no longer followed.

Patient ID Number _____
Rev. 3 11/15/90

Form # 03
Page 5 of 6

**Modification of Diet in Renal Disease Study
Screening Form**

- 101. Date this form completed..... _ _ / _ _ / _ _
- 102. Certification number of person filling out this form _ _ _ _ _
- 103. Date form entered..... _ _ / _ _ / _ _
- 104. Certification number of data entry person _ _ _ _ _

**Modification of Diet in Renal Disease Study
DEMOGRAPHIC AND BASELINE EXAMINATION FORM**

This form is to be completed by the study coordinator, physician and dietitian at the initial Baseline Visit (B0).

QUESTION # INSTRUCTIONS

8. Enter the patient's birthdate (MM/DD/YY). A complete date must be entered into Datalex. If the day of the month is unknown, enter a 15. If the month is unknown, enter a 06. If year is unknown, enter blank.
9. It is important that females are determined to be post menopausal or surgically sterile before answering a 3. Menstruating females must have a pregnancy test before all GFR measurements.
12. Enter the code corresponding to the type of work the patient does. If the patient is not presently working, indicate the code for his or her most recently occupied position. Attached to the instructions is the complete alphabetical list of occupations and their appropriate codes. Enter a 9 if the occupation is unknown. Enter an 8 if the patient has never worked outside the home.
- 14.e. Illness refers to any type not just related to renal disease.
- 16-17. The following is the list of income categories:
1 = < \$7,500 4 = 25,000 - 39,999
2 = 7,500 - 14,999 5 = 40,000 - 49,999
3 = 15,000 - 24,999 6 = 50,000 - 74,999
7 = ≥ 75,000
9 = unknown
- 21-37. The study physician should have this form while completing the patient's history and physical exam.
31. If the patient does not smoke, enter 00.00.
32. This is in regards only to present smoking. If not presently smoking, enter 00.
35. The physical exam may be done any time from the Screening Visit to 1 day after the Baseline 0 Visit.

Modification of Diet in Renal Disease Study
DEMOGRAPHIC AND BASELINE EXAMINATION FORM

38. Standard Body Weight should be completed by the dietitian. Instructions for its completion are included in the Nutrition portion of the Manual of Operations.
- a. The patient's height should be recorded in centimeters, rounded to the nearest tenth of a centimeter. Only values between 120 and 200 may be entered. It must be measured twice, and the average used. For more specific instructions see the Nutrition portion of the Manual of Operations.
 - b. The right elbow breadth should be recorded in centimeters rounded to the nearest tenth. Refer to the Nutrition portion of the Manual of Operations.
 - c. The patient's frame size is determined from his or her elbow breadth. Refer to the Nutrition portion of the Manual of Operations for table and instructions.
 - d. The patient's actual body weight should be entered in kilograms, rounded to the nearest tenth. It must be measured twice and the average used. Refer to the Nutrition portion of the Manual of Operations for further instructions. The dietitian does not need to be the person to complete this item.
 - e. The standard weight is determined according to height, sex, and frame size. Refer to the Nutrition portion of the Manual of Operations.
 - f. (average from part 'd'/answer to part 'e') multiplied by 100. The value should be rounded to a whole percentage point, then right justified.
 - g. If the value in part 'f' is greater than or equal to 80% and less than or equal to 160%, then enter a 2. If it is outside this range, enter a 1.
 - h. Enter dietitian's certification number.
 - i. Enter whether the patient wants to lose, gain or stay the same weight.
39. The code number from the attached list, the dosage, IN THE CORRECT UNITS, and the number of times/day should be listed for each drug the patient is taking presently.

Drug doses - If patient receives a dose which includes decimals (12.5 2 times a day) you must enter the decimal point in one of the dashes provided. Similar to completing Forms 24 and 25. If a dose is truly missing, enter 999999.

**Modification of Diet in Renal Disease Study
DEMOGRAPHIC AND BASELINE EXAMINATION FORM**

The following codes should be used as "times per day" if a drug is taken at unusual frequencies:

- 87 = four times per month
- 88 = once every 5 days
- 89 = two weeks/month
- 90 = 5 times per week
- 91 = every other day
- 92 = once a week
- 93 = 3/week
- 94 = 3 weeks/month
- 95 = once a month
- 96 = twice a week
- 97 = once every 3 weeks
- 98 = 4 times per week

A

Accountants (C.P.A.) - 1
 Accountants (Not C.P.A.) - 2
 Actors and Showmen - 3
 Actuaries - 1

 Advertising Agents - 3
 Advertising Directors - 2
 Advertising Owners - 2
 Agronomists - 1
 Aides, Hospital; Nurses Aide - 6
 Aircraft Maintenance - 4
 Air Line Pilot/Traffic Controller - 2

 Air Line Reservationist - 4
 Amusement Park Workers (Bowling alley,
 Pool Hall) - 7
 Anesthetists - 1
 Antenna Installers - 5
 Anthropologists - 1
 Antique Dealers - 3
 Apprentices, Electricians, Painters,
 Steam Fitters, Tool Makers - 6
 Architects - 1
 Archetectural Draftsmen - 2
 Archivists - 1
 Army, M/Sgt./Navy C.P.O. - 3
 Art Gallery - 3
 Art Historian - 2
 Art Illustrator - 3
 Artists (commercial) - 3

 Artist (portrait) - 1
 Artists (unspecified) - 3
 Asbestos Workers - 6

 Ash Removers - 7
 Assembly Line Workers - 6
 Assessment Counselors - 2
 Assistant Director: Student Union,
 Office of Student/Placement - 2
 Assistant Manager: Banking, Grocery,
 Music Store, Orchestra Hall, - 3
 Small Loan Co. (unspecified)
 Assistant Manager - Sm. Business - 4
 Assistant Neuro-Psychologists - 3
 Assistant Psychologists - 2
 Assistant Registrar, University - 3
 Assistant Superintendent of Schools
 City, County, State - 1

 Assistant Trainer, Racetrack - 6

 Astronaut - 1
 Astronomer - 1
 Attendants (parking lots) - 7
 Audio Visual (unspecified) - 4
 Audiometrician - 4

 Auditors - 1
 Authors - 2
 Auto Accessories (sm. business) - 3
 Auto Body Repairs - 5
 Automobile Designer - 1
 Automobile Underwriter - 3
 Aviation Metalsmith - 4
 Avon Products Saleswoman - cosmetics,
 wigs, self-employed - 4
 Awnings (sm. business) - 3

B

Baby Sitters - 7
Bacteriologists - 1
Bakers - 5
Bakery (sm. business) - 3
Bailiff - 3
Bank Clerks and Tellers - 4
Bank Presidents/Vice Presidents - 1
Banker (unspecified) - 2
Barbers - 5
Bartenders - 6
Beautician/Cosmotologists - 5
Beauty Shop (sm. business) - 3
Bell Diver - 4
Bill Collectors - 4
Bingo Tenders - 6
Biochemical Technicians - 4
Blacksmiths - 5
Boatyard (sm. business) - 3
Boiler Makers - 5
Bookbinders - 5
Bookie or Numbersperson - 3
Bookkeepers - 4
Boy Scout Executives - 2
Brakemen, R.R. - 5
Branch Managers - 2
Brewers - 5
Brick Layers/Brick Mason - 5
Broadcast Engineers - 3
Brokerage, Insurance - 3
Brokerage Salesmen (Stock Broker) - 2
Brokers (large - over \$100,000) - 1
Budget Analysts (wage/systems) - 2
Building Superintendents (custodian) - 6
Bullodzer Operators - 5
Bus Boys - 7
Bus Drivers - 6
Business Administration (unspecified) - 2
Business Machine Operators, Offices - 4
Businessmen (unspecified) - 2
Butchers - 5
Buyers - 2

C

Cabinet Workers - 5	Cigar Makers -5
Cafeteria Workers - 7	Cigarette Machines - 3
Cafeteria Workers (Public Schools) - 6	City Planners - 2
Car Cleaners, R.R. - 7	Civilian Workers - 3
Car Dealers - 3	Claims Adjustors - 4
Car Helpers, R.R. -7	Claims Examiners - 4
Carriers, Coal - 7	Cleaning Shops - 3
Carpenters - 5	Clerical - Bookbinders, State Clerks, Government, Hospital Admitting, Insurance, Library Desk, Railroad - 4
Carpet Cleaners - 5	Clerical or Stenographic Secretaries - 4
Casters (Foundry) - 5	Clerical Supervisors - 3
Caterers (small business) - 3	Clergymen (not trained) - 3
Cattle Dealers - 3	Clergymen (professionally trained) - 1
Cement Finishers - 5	Clerk Accountants - 3
Chain Makers - 5	Clinical Laboratory Technicians - 4
Chairwomen - 7	Clinical Supervisors - ?
Chauffeurs - 6	Clothing (sm. business) - 3
Checkers - 6	Clothing Salespersons - 4
Cheese Makers - 5	Clothing Store Owner (\$100,000) - 2
Chefs - 5	Coaches and Teachers - 2
Chemical Engineers - 1	Coal Business - 3
Chemical Processmen - 5	Coal Miners - 6
Chemical Sales - 2	Coal Processing Firemen - 6
Chemists - 1	Coders - 4
Chief Clerks - 3	Coin Machine Fillers - 6
Childbirth Instructors - 3	College Administrators (low level) - 2
Child Care Workers - 3	College Adminstrators (major) Dean/President - Regent/Provost - 1
Chiropodist/Podiatrists - 2	College Personnel Services - 3
Chiropractors - 2	Color Technicians - 4
Choir Masters - 3	County Welfare Directors - 1
Commercial Drivers - 5	County Workers - 6
Community Development - 2	Court Recorders - 3
Companion - 6	

C (continued)

Compositors - 5
Comptometer Operators - 4
Computer Programmers (unspecified) - 2
Computer Systems Analysts - 2
Concern Managers - 3
Conductors, R.R. - 4
Construction - 7

Consultants, Investment/Insurance - 2
Contractors (large - over \$100,000) - 1
Contractor (Builders) - 2
Contractors (Carpenters, Electrical, - 3
Flooring, Plastering, small)
Contractors (unspecified) - 2
Contractors (\$100,000) - 2
Convalescent Homes - 3
Cooks, short order - 6
Cooks, unspecified - 6
Cook's Helpers - 7
Coordinator of Services for the blind - 2
Coordinator: Telephone Company - 3
Copy Boy - 7
Core Makers - 5
Correction Officers - 2
Cosmetology Teachers - 3
Counter men - 7
County Agents (agriculture) - 2
County Building Supervisor - 3

Cowboys - 6
Craftsmen - 5
Credit Managers - 3
Credit Supervisors: Gas, Electric Co. - 3
Crib Attendants - 6
Criminologists - 1
Custodial: Engineer/Stationary,
Engineer Maintenance - 5
Custodians - 7
Cutters - 5
Cytotechnicians - 2

D

Dairy Owners - 1
Dairy Workers - 7
Dancer - Ballet - 2

Director of Community House - 2
Disability Examiners - 2
Dishwashers - 7

D (continued)

Dancing Teacher - 3	Dispatchers, R.R. train - 3
Data Analysts - 2	District Managers - 2
Data Preparation Managers - 2	Draftsmen/Mechanical Draftsmen - 4
Data Processing - 4	Driving Teacher - 4
Dealer Representatives: Auto - 3	Door Fitters - 5
Deck Hands - 7	Dressmakers (machine) - 6
Decorating - 3	Domestics - 7
Deisel Engine Repairs, Maintenance (trained) - 5	Dog Supplies (sm. business) - 3
Deisel Mechanics - 5	Dry Goods (sm. business) - 3
Deisel Shovel Operators - 5	Driver/Salesman (e.g. Bread) - 4
Delivery Men - 6	Drugstore Bookkeeper/Clerk - 4
Demolition - 5	
Demolition Firm - 3	
Display Worker - 5	
Dental Assistants - 4	
Dental Hygienists - 3	
Dental Technicians - 4	
Dentists - 1	
Deputy Shriffs - 3	
Die Makers (own business) - 2	
Dietary Aide - 4	
Dietician - 2	
Digital Computer (technician) - 4	
Director: Government Committion on Employment, Religious Education - 2	
Director: Nursery School - 2	

E

Economists - 1	Expeditors, Factory - 4
Editors - 1	Experimental Testers - 4
Editors, company magazine - 2	Express Company Owners (\$100,000) - 2
Editorial Assistants - 2	Extension Home Agents - 3

E (continued)

Education Administration (not major) - 2	Exterminators - 5
Educational Specialists - 2	
Egg Candler - 6	
Electrical Technicians - 4	
Electricians - 5	
Electrotypists - 5	
Elevator Operators - 6	
Employment Counselors - 2	
Employment Interviewers - 4	
Engineers (not a college graduate) - 2	
Engineering (college graduate) all kinds including Industrial Design - 1	
Engravers - 5	
Engraving Business - 3	
Enlisted Men, Military Services - 6	
Entomologists - 1	
Entomology Research - 2	
Entrepreneurs (manager/promoter) - 2	
Equitation Instructors - 3	
Estate Managers (V.A.) - 2	
Executive Assistants - 2	
Executive Managers, Government Officials, minor e.g., Internal Revenue Agents - 2	

F

Factory Storekeeper - 4	Forest Service Technicians - 4
Factory Supervisor - 4	Forest Service Technician/Tree Surgeon - 2
Factory Worker (semi-skilled) - 6	Foresters - 1
Farm Helpers - 7	Fruits, wholesale (\$100,000) - 2
Farm Management Specialists - 1	Furniture Business (\$100,000) - 2
Farm Managers - 2	Furniture Business (small) - 3
Farm Owners (\$25,000 - 35,000) - 3	Foundry Business (small) - 3
Fashion Designers - 3	Foundry Workers - 6

F (continued)

Feed - 3
Filers, Benders, Buffers - 6
Filling Machines (wholesale drug) - 6
Film Makers - 3
Film Processors - 5
Finance companies, Local - 3
Finance Writers - 2

Fire Extinguishers - 3
Fireman, City, R.R. - 5
Fisherman (Clam Diggers) - 7
Fitters, Gas; Steam - 5
Five and Ten - 3
Floor Workers - 6
Florists - 3
Flower Shops - 4
Food Equipment - 3
Food Products - 3
Food Service Workers - 7
Foreman: Apple processing, maintenance, machine shop, mine - 5
Foreman: Construction; Dairy - 5
Foreman: Newspaper, City, R.R., Ford Motor, etc. - 4

Funeral Directors - 3
Funeral Assistants - 5
Furriers - 5
Fur Trappers - 6
Fork Lift Operators - 6
Freight Handlers - 7
Farmers - smaller tenants with
little equipment - 6
Farmers - Share Croppers - 7

G

Garage - 3
Garage and Gas Station Assistants - 6
Garbage Collectors - 7
Gardners, Landscape (trained) - 5
Garment Inspectors - 6
Gasoline Brokers and Distributors - 3
Gas Station - 3
Gastric Analysts - 1
Geodetic Sciences - 1
Geologists - 1
Girls Counselors - 2

G (continued)

Glass Blowers - 5
Glassware - 3
Glass Worker/Glazier - 5
Government employees (unspecified) - 4
Graduate Resident Advisor - 2
Grave Diggers - 7
Greenhouse Workers - 6
Grinders - 6
Grocer - General (\$6,000 - \$35,000) - 3
Grocery Store (unspecified) - 5
Guage Makers - 5
Guards, Doorkeepers, Watchmen - 6
Guidance Counselors - 2
Gunsmiths - 5

H

Hairdressers - 6
Hair Stylists - 5
Hammer Helpers - 7
Hardware (unspecified) - 2
Hat Maker - 5
Health Educators - 2
Health Inspectors - 4
Hearing Technical Assistants - 3
Heat Treaters - 5
Historian (museum) - 1
Hod Carriers - 7
Hog Killers - 7
Home Economists - 2
Horseback Riding (sm. business) - 3
Horseback Riding Assistants - 6
Horticulturists - 5
Hospital Administrators - 1

H (continued)

Hospital Workers (unspecified) - 7
Hotel Proprietors - 3
Housekeepers - 6
Housing Assistants - Public Housing - 4
House Moving Company - 3
Hydrology - 1

I J & K

I

Import - Export (unspecified) - 2
Industrial Relations - 2
Industrial Workers - 6
Inspectors: Boiler Insurance Company & - 4
Fire, Government, R.R.,
Factory, etc.
Installers: Electric Appliances - 5
Institute of Music - 3
Insurance Executives - 2
Insurance Adjustors, Inspectors, - 3
Consultants
Insurance Agents - 3
Interior Decorators - 3
Interpretors, Court/U.N. - 3
Interviewers for Crippled Children's - 2
Agency
Inventors - 3
Investigators - 4
Iron Makers - 5

J

Janitors, Sweepers - 7
Jewelers (\$100,000) - 2
Jewelry (\$6,000 - \$35,000) - 3
Job Interviewers - 4
Journalists - 2
Judges (Superior Courts) - 1

K

Key Boy - 6
Kiln Foreman - 5
Kitchen Helpers - 7

L

Laboratory Aides - 4
Laboratory Assistants - 3
Laboratory Technicians - 4
Laborers (Construction) - 7
Laborers (unspecified) - 7

Local Treasurers - R.R. - 1
Locksmiths - 5
Locomotive Engineers, R.R. - 4
Longshoremen - 7
Loom Fixers - 5

L (continued)

Labor Leader/Official - 2
Labor Market Analysts - 2
Labor Relations (Consultants) - 2
Landscape Planner - 3
Landscapeper - 3
Large Business, e.g. Director/President
Vice President/Assistant Vice President/
Executive Secretary and Treasurer - 1
Laundromat - 3
Laundry Workers - 7
Lawyers - 1
Law Enforcement Officers - 5
Lead Burners - 6
Leasing or Rental Agents - 4
Lens Grinders - 5

Librarian - 2
Library Aides, Technicians - 3
Library Page - 6
Licensed Pratical Nurse - 3
Life Guards - 4
Linemen Utility - 5
Linetype Operators - 5
Linoleum Layers (trained) - 5
Lithographers - 5
Lumber Dealers - 1
Lumber Delivery Men - 6
Lumberjacks - 7
Lumbermen (unspecified) - 3

M

Machinery Broker - 3
Machinist (trained) - 5
Mail Handler - 5
Maintenance (Building) - 6
Maintenance Workers, R.R. - 5
Managers Carpet Workroom - 5
Managers of Law Firm - 1
Management - Hotel - 2
Management Trainee: Sales - 3
Manufacturer (unspecified) - 2
Manufacturer Representatives - 2
Manufacturing (small business) - 3
Marketing - 1
Marketing Managers for Electric Company - 3
Makers (newspapers) - 6
Masons - 5

Merchant Marines - 5
Messengers - 7
Metal Fabrication - 6
Metallurgists - 1
Meter Readers - 6
Microfilmers - 4
Midwife (unregistered) - 3
Military Commissioned Officers, - 1
Majors and above
Military Commissioned Officers, - 2
Lieutenants, Captains, etc.
Military Officers (unspecified) - 2
Milkmen - 5
Millwrights - 5
Miners - 6
Models - 3

M (continued)

Masseurs - 5
Mathematicians - 1
Meat Cutters and Packers - 6
Meat Department (unspecified) - 6
Meat Wholesalers - 2
Mechanics (trained) - 5
Medical Assistants - 3
Medical Illustrators - 3
Medical Records Librarian - 4
Medical Technologists - 4
Merchandise Coordinator - 4
Merchandise Department Store - 2
Merchant Helpers - 6

Model Cities workers (City Government) - 4
Monuments (small business) - 3
Morticians - 3
Motor Mechanics - 5
Moulder (trained) - 5
Movers - 6
Municipal Tax collectors - 4
Music Teachers - 3
Music Therapists - 3
Musicians (symphony) - 2
Musicians (unspecified) - 2

N & O

N

Nasa Space Vehicle Recovery - 1
Neck Tie Worker - 6
Newstand - 4
Newspaper Feature Syndicate Executive - 2
Nursery School Teacher - 3
Nurses - 2
Nurses Assistant - 3
Nursing Technician - 4

O

Occupational Therapist (Sensio motor - 2
treatment techniques)
Office Assistant, Office Worker - 4
Office Managers/Managers of - 2
Companies, etc.
Oil Field Worker - 6
Oil Treater - 6
Oiler, R.R. - 6
Operating Engineers - 4
Operator (factory machines) - 6

Operation Room Technician - 4
Operator, P.B.X. (private branch - 4
exchange)
Operator (Sanitary District) - 7
Optician - 2
Optometrist - 1
Oral Hygienist - 3
Organist - 3
Orthopedic G.M.S. - 1
Owner: Auto body repair business,
Butcher shop, General store,
Music store, Nursery, Small
business - 3

P

Package store (liquor) - 3	Physicians - 1
Packager - 6	Physicists, Research - 1
Painter - 5	Piano Builders - 5
Painting Contractor - 3	Piano Teachers - 3
Paper Hangers - 5	Piano Tuners - 5
Parole Officer - 2	Pipefitters - 5
Passenger Agents, R.R. - 3	Placement Agency Workers - 2
Patrolmen, R.R. - 5	Placement Directors - 2
Pattern and Model Makers - 5	Planning Analyst - 2
Peace Corp. Volunteer - 2	Planning Coordinators - 3
Peddler - 7	Planning Consultants - Mental Health - 2
Penologist - 1	Plant Managers - 2
Personal Maid - 7	Plant Pathologists - 1
Personnel Administrator - 4	Plastic Business - self-employed - 3
Personnel Interviewer - 3	Platform Men, R.R. - 7
Personnel Manager - 2	Plater - 5
Personnel Work (unspecified) - 4	Playground Assistants - 5
Personnelmen, Employment Managers - 3	Plumbers - 5
Petroleum Jobbers - 3	Plumbing Business - 3
Pharmacists - 2	Plywood Workers - 6
Pharmacologists - 1	Police Chief, Sheriff - 2
Photographers - 3	Police Detectives - 2
Photographic Advisors - 2	Policemen, City - 5
Physical Education Teacher - 2	Polishers - 6
Physical Therapists - 2	Politician (unspecified) - 2
Physical Therapy Assistants - 3	Porters - 7
Physical Therapy Instructors (college level) - 1	Post Office Clerks - 4
Physical Therapy Instructors (non-college level) - 2	Portal Assistants - 4
Postman - Letter Carriers - 5	Publishers (unspecified) - 2
Postmasters - 2	Pulpwood Producers - 3
Poultry Producers - 3	Pump Operators - 6
Practical Nurses - 6	Punch Press Operators - 6

P (continued)

Presser, Clothing - 6
Presser Supervisors - 5
Pressmen - 5
Principal (elementary & high school) - 2
Printers - 5
Prison Guards - 5
Private Secretaries - 3
Probation Officers - 2
Production, Automobiles - 6
Production Managers - 2
Production Planners - 3
Program Directors, Rehab. Center - 2
Professional Sports, e.g. baseball, golf - 3
Proofreaders - 4
Psychiatrists - 1
Psychological Research - 2
Psychologist, practicing - 1
Psychometrist/Psychological Technician - 2
Public Health Officers (M.P.H.) - 2
Public Work - Heavy Equipment - 5
Publicity & Public Relations (fundraising) - 3

R

Radio, TV Announcer - 3
Radio, TV Maintenance - 5

Railroad Agent - 4
Railroad Station Manager - 3
Railway Clerk - 4
Rancher - 2
Real Estate business (small) - 3

Restaurant (small) - 3
Restaurant Manager - 3
Restaurant (unspecified) - 6
Roll Grinder-Steel Mill - 5
Roofer - 6
Roofer Helper - 7
Roofing Contractor - 3
Rope Splicer - 5

R (continued)

Real Estate Broker (\$100,000) - 2
Real Estate Management - 3
Receiver and Checker - 6
Receptionst/Hostess - 4
Record and Radio (small business) - 3
Recreation Director - 2
Recreation Therapist - 2
Reforestation (plant new trees) - 3
Registered Midwife - 2
Rehabilitation Counselor - 2
Rehabilitation Supervisor - Chief O.T. - 2
Relief (worker) - 6
Relief (public & private) - 7
Religious Educator - 2
Repairman, Home Appliances - 5
Reporter, Court - 3
Reporter, Newspaper - 3
Research Assistant - University (full-time) - 2
Research Director, Large firm - 1
Reservoir Caretaker - 6
Residential Appraiser - 3

Route Manager - 4
Rubber Worker - 6
Rug Business (\$100,000) - 2
Rural Letter Carrier - 5

S

Sales Supervisors - 4
Sales Clerks - 4
Sales Consultants - 3
Sales Distribution - 3
Sales Engineers, National Concern - 2
Sales Managers, National Concern - 2
Sales Representatives - 3
Salesmen (unspecified) - 3
Sand Blasters - 6
Sanders - 6

Shipyards Safety Men - 6
Shirt Folders - 7
Shoe Store - 3
Shoe Factory Employees - 6
Shoe Repairmen, (trained) - 5
Shoe Shiner - 7
Shop Managers - 3
Sign Writers - 5
Signs (small business) - 3
Signal Men, R.R. - 6

S (continued)

Saw Mill Worker - 6
Saw Milling - small operators - 3
School Psychologists - 2
Scientists (unspecified) - 1
Scrap Metal Dealer - 3
Seamstress - 5
Secretary: Medical, Trilingual, Bilingual, - 3
Executive, Legal Service Manager
Section Heads: Federal, State &
Local Government - 3
Section Heads: Large Business & Industries - 3
Security Guards - 6
Self-employed (unspecified) - 3
Service Managers - 3
Service Representatives: Telephone Co. - 3
Set Up Men (Factories) - 6
Sewage Plant Attendant - 6
Shapers - 6
Sheet Metal Workers (trained) - 5
Shipping Clerk - 4
Shipsmith - 5

Statisticians - 1
Steel Cutters - 5
Steelworkers (not skilled) - 6
Stereotypers - 5
Stevedores - 7
Steward, Club - 5
Steward, Shop, Union - 4
Stewardess - 3

Singer - 3
Skein Winder - 6
Skid Puller - 7
Slitter Operator - 6
Snack Bar Operator (owner) - 4
Social Security Administrators - 3
Social Work Assistants (no training) - 6

Social Workers - 2

Soil Conservation - 2
Solderer, Factory - 6
Sorter, (rag & salvage) - 7
Sound Recordist - 1
Sound Recorder (self-employed) - 3
Special Agents, (FBI, CIA, IRS) - 2
Speech Therapists - 2
Sprayer, Paint - 6
Stagehand - 7
State Director, Rehab. - 1
State Highway Employees - 4
Stationary Engineer (licensed) - 4

Supplymen (Telephone) - 6
Surveyors - 3
Swimming Instructors - 3
Switchboard Operators - 4
Switchmen, R.R. - 5
Symphony Conductor - 1
Systems Manager - 3
Systems Salesmen - 3

S (continued)

Stillman, Oil Company - 5
Stock Handlers - 7
Store Managers (Chain) - 3
Store Owners (\$100,000) - 2
Strander (wire machine) - 6
Street Cleaners - 7
Strippers (rubber factory) - 6
Student Coordinators - 3
Student Aides - 3
Superintendent of Schools: City/County/State - 1
Superintendent: Circulation Dept., Newspaper, - 3
Creamery, R.R.
Superintendent: Coal Mine, Stock, Western Union - 4
Supermarket Managers - 3
Supervisors: Hospital, Housekeeping - 4
Supervisor: Maintenance - 4
Supervisor: Nursing Administration - 2
Supervisor: Production Planning - 3
Supervisor: United States Postal - 3
Supervisor: Utilities/Factories - 4

T

Tailor Shop (owner) - 4	Tool Designer - 3
Tailor (trained) - 5	Tool and Die Maker - 5
Tally Men - 6	Tool Grinder - 5
Tavern Owner - 3	Tool Maker - 5
Taxi Company - 3	Tour Guide - 4
Taxi Driver - 6	Tower Operator - 5
Teacher Aide - 3	Tower Operator, R.R. - 4
Teacher (elementary, high school) - 2	Track Supervisor - 5
Teacher (university, college) - 1	Tractor Driver - 6

T (continued)

Technical Assistants - 4	Tractor & Trailer Trans. - 5
Technical Consultant - 2	Traffic Manager - 3
Technical Writer - 2	Trainmen, R.R. - 6
Technician in Agricultural Services - 2	Travel Agent - 3
Technician: Personnel, Engineering - 2	Treasurer - Credit Union - 3
Telegraph Operator - 5	Tree Sorter - 6
Telephone Operator - 5	Tree Trimmer - 5
Telephone Company Supervisor - 4	Truck Dispatcher - 4
Telephone Repairmen - 5	
Teletype Operator - 5	Truck Driver (general) - 6
Tester - 6	Trucking business - 3
Textile Worker - 6	Trucks & Tractors - 3
Theatre Owner (\$100,000) - 2	Truckmen, R.R. - 7
Tile Setters - 5	Trust Administrative Asst. - 3
Timekeeper - 4	Turntable Operator, R.R. - 6
Timer - 6	Tutor - 3
Tire Moulder - 6	T.V. Cameramen - 3
Tire Shop - 3	
Title Searcher - 3	Typist/Varitypist, Key punch - 4
Toll Station Supervisor - 4	Typographer - 5

U V W X Y & Z

U

Underwater Ordinance Workers - 5
Underwriters: Insurance - 3
Unskilled Factory Workers - 7
Upholsterer (trained) - 5
Upholstery (small business) - 3
Urban Corporations - 6
Ushers - 6
Utility Men (automobiles) - 6

V

VA Adjudicators - 2
Vending Stand Operators/Food Service - 4
Veterinarians (Vet Surgeons) - 1

W

Waitress ("Hash House") - 7
Waitress/Waiter ("Better Places") - 6
Wall Paper Hangers - 5
Wardens - 3
Warehouse Clerks - 4
Warehousemen - 7
Washers (cars) - 7
Waste Product Recycling - 5
Watch Makers - 5
Weighers - 6
Weavers - 5
Weld Press Operators - 6
Welders - 5

Welders (spot) - 6
Wholesale Order Filler - 4
Wholesale Outlet - 3
Wholesaler (unspecified) - 2
Winder (machine) - 6
Window Cleaner - 7
Window Shades (small business) - 3
Window Trimmer (store) - 4
Wine Bottlers - 6
Wire Chief Technicians - 5
Wiredrawer (machines) - 6
Wood Workers (machine) - 6
Woodchoppers - 7
Woodworking Factory (small) - 3
W.P.A. Workers - 7
Wrappers (stores & factories) - 6
Writer/Author, Newspaper or unspecified - 2

X

X-Ray Aides - 5

Y

Yard Masters, R.R. - 3
Yard Supervisors, R.R. - 5
Y.M.C.A. Sports Directors - 2
Youth Counselors - 2
Youth Group Directors - 2
Youth Programmers - 3

Z

Zoologists - 1

MDRD DRUG LIST

			<u>Code Number</u>
I.	<u>ANTIBIOTICS</u>		
A.	Anti Protozoal Agents		
	1. Emetine Hydrochloride	mg	00010
	2. Metronidazole (Flagyl)	mg	00020
B.	<u>Anti Helmintics</u>		
	1. Piperazine Citrate (Antepar)	mg	00030
	2. Praziquantel (Biltricide)	mg	00040
	3. Quinacrine Hydrochloride (Antabrine)	mg	00050
	4. Thiabendazole (Mintezol)	mg	00060
C.	<u>Antifungals</u>		
	1. Griseofulvin (Fulvicin)	mg	00070
	2. Ketoconazole (Nizoral)	mg	00080
	3. Nystatin (Mycostatin)	units	00090
	4. Nystatin - mouthwash	cc	00091
D.	<u>Antibacterial Agents</u>		
	1. Cephalosporins		
	a. Cefaclor (Ceclor)	mg	00100
	b. Cefadroxil (Duricef)	mg	00110
	c. Cephalexin (Keflex)	mg	00120
	d. Cephradine (Anspor)	mg	00130
	2. Chloramphenicol (Chloromycetin)	mg	00140
	3. Erythromycin	mg	00150
	4. Penicillins		
	a. Penicillin G Benzathine (Bicillin)	units	00160
	b. Penicillin G Potassium (Pentids)	units	00170
	c. Penicillin V Potassium	mg	00180
	d. Cloxacillin Sodium (Cloxapen)	mg	00190
	e. Dicloxacillin Sodium (Dynapen)	mg	00200
	f. Nafcillin Sodium (Unipen)	mg	00210
	g. Oxacillin Sodium (Prostaphlin)	mg	00220
	h. Amoxicillin	mg	00230
	i. Amoxicillin and Clavulanate Potassium (Augmentin)	mg	00240
	j. Ampicillin	mg	00250
	k. Carbenicillin Indanyl Sodium (Geocillin)	mg	00260
	5. Tetracycline		
	a. Demeclocycline Hydrochloride (Declomycin)	mg	00270
	b. Doxycycline Calcium (Vibramycin)	mg	00280
	c. Oxytetracycline Hydrochloride (Terramycin)	mg	00290
	d. Tetracycline	mg	00300
	6. Clindamycin Hydrochloride (Cleocin)	mg	00310
	7. Vancomycin (Vancocin)	mg	00320
	8. Anti Tuberculous Medication		
	a. Ethambutol (Myambutol)	mg	00330
	b. Isoniazid	mg	00340
	c. Rifampin (Rifadin)	g	00350

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D.	<u>Antibacterial Agents (continued)</u>		
9.	Nalidixic Acid	mg	00355
10.	Nitrofurantoin (Macrochantin)	mg	00360
11.	Trimethoprim	mg	00370
12.	Co-trimoxazole (Bactrim) (Septra)	tablets	00380
13.	Bactrim Double Strength	tablets	00381
14.	Azulfidine (Sulfasalazine)	grams	00382
15.	Gantricin (Sulfisoxazole)	grams	00383
E.	<u>Antiviral Agents</u>		
1.	Acyclovir (Zovirax)	mg	00390
2.	Amantadine Hydrochloride (Symmetrel)	mg	00400
F.	<u>Antimalarial</u>		
1.	Chloroquine Hydrochloride	mg	00410
2.	Primaquine Phosphate	mg	00420
3.	Pyrimethamine (Daraprim)	mg	00430
4.	Quinine Sulfate	mg	00440
G.	<u>Other Antibiotic</u>	mg	00450
1.	Ciprofloxacin	grams	00460
2.	Norfloxacin (Noroxin)	mg	00470
II.	ANTINEOPLASTIC AGENTS		
A.	Azathioprine (Immunan)	mg	10010
B.	Busulfan (Myleran)	mg	10020
C.	Chlorambucil (Leukeran)	mg	10030
D.	Cyclophosphamide (Cytosan)	mg	10040
E.	Hydroxyurea (Hydrea)	mg	10050
F.	Lomustine (CeeNu)	mg	10060
G.	Megestrol Acetate (Megace)	mg	10070
H.	Melphalan (Alkeran)	mg	10080
I.	Mercaptopurine (Purinethol)	mg	10090
J.	Methotrexate	mg	10100
K.	Mitotane (Lysodren)	mg	10110
L.	Pipobroman (Vercyte)	mg	10120
M.	Procarbazine Hydrochloride (Matulane)	mg	10130
N.	Tamoxifen Citrate (Nolvadex)	mg	10140
O.	Testolactone (Teslac)	mg	10150
P.	Thioguanine	mg	10160
Q.	Uracil Mustard	mg	10170
R.	Other	mg	10180
III.	CARDIOVASCULAR DISORDER		
A.	<u>Inotropic Agents</u>		
1.	Digitoxin (Crystodigin)	mg	20010
2.	Digitalis	mg	20020
3.	Digoxin (Lanoxicaps) (Lanoxin)	mg	20030

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B.	<u>Antiarrhythmic Agents</u>		
1.	Disopyramide Phosphate (Norpace)	mg	20040
2.	Procainamide Hydrochloride (Procan) (Pronestyl)	mg	20050
3.	Quinidine Gluconate (Quinight, Cardioquin)	mg	20060
4.	Tocainide Hydrochloride (Tonocard)	mg	20070
5.	Encainide	mg	20071
6.	Amiodarone	mg	20072
C.	<u>B-Blockers</u>		
1.	Atenolol (Tenormin)	mg	20080
2.	Labetalol Hydrochloride (Normodyne)	mg	20090
3.	Metoprolol Tartrate (Lopressor)	mg	20100
4.	Nadolol (Corgard)	mg	20110
5.	Pindolol (Visken)	mg	20120
6.	Propranolol Hydrochloride (Inderal)	mg	20130
7.	Timolol Maleate (Blocadren)	mg	20140
8.	Betaxolol Hcl (Kerlone)	mg	20141
9.	Acebutolol (Sectral)	mg	20142
10.	Penbutolol (Levatol)	mg	20143
D.	<u>Calcium Channel Blockers</u>		
1.	Diltiazem Hydrochloride (Cardizem)	mg	20150
2.	Nifedipine (Procardia)	mg	20160
3.	Verapamil Hydrochloride (Calan, Isoptin)	mg	20170
4.	Nicardipene (Cardene)	mg	20171
5.	Isradipine (DynaCirc)	mg	20172
6.	Plendil (Felodipine)	mg	20173
E.	<u>Anti-Hypertensive Agents</u>		
1.	<u>Central Acting Agents</u>		
a.	Clonidine (Catapres)	mg	20180
b.	Methyldopa (Aldomet)	mg	20190
c.	Guanabenz Acetate (Wytensin)	mg	20200
d.	Tenoretic	mg	20201
2.	<u>Postganglionic adrenergic blocking agents</u>		
a.	<u>Rauwolfia Alkaloids and combinations</u>		
1.	Reserpine (Serpalan) (Serpasil)	mg	20210
2.	Reserpine and Hydrochlorothiazide	mg	20220
3.	Reserpine and Chlorthalidone (Regroton)	mg	20230
4.	Deserpidine (Harmony)	mg	20240
5.	Alseroxylon (Rauwiloid)	mg	20250
6.	Rescinnamine (Moderil)	mg	20260
7.	Rauwolfia Serpentina (Hiwolfia)	mg	20270
b.	Guanadrel Sulfate (Hylorel)	mg	20280
c.	Guanethidine Monosulfate (Ismelin)	mg	20290
3.	<u>Ganglionic Blocking Agent</u>		
a.	Mecamylamine Hydrochloride (Inversine)	mg	20300

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4.	<u>MAO Inhibitors</u>		
	a. Pargyline Hydrochloride (Eutonyl)	mg	20310
5.	<u>ACE Inhibitors</u>		
	a. Captopril (Capoten)	mg	20320
	b. Enalapril (Vasotec)	mg	20330
	c. Zestril (Lisinopril)	mg	20331
	d. Other	mg	20332
	e. Ramipril (Altace)	mg	20333
6.	<u>Vasodilators</u>		
	a. Diazoxide (Proglycem) (Hyperstat)	mg	20340
	b. Hydralazine (Apresoline)	mg	20350
	c. Minoxidil (Loniten)	mg	20360
	cl. Minoxidil - Topical (conversion 20 mg/ml)	ml	20361
	d. Prazosin Hydrochloride (Minipress)	mg	20370
	e. Terazosin (Hytrin)	mg	20371
	f. Doxazosin Mesylate (Cardura)	mg	20372
	g. Isoxsuprine	mg	20373
7.	<u>Other</u>		
	a. Tenex (Guanfacine Hydrochloride)	mg	20376
F.	<u>Nitrates</u>		
	1. Erythryl Tetranitrate (Cardilate)	mg	20380
	2. Isosorbide Dinitrate (Isordil)	mg	20390
	3. Nitroglycerin - sublingual and paste, patch	mg	20400
	4. Pentaerythritol tetranitrate (Duotrate)	mg	20410
G.	<u>Diuretics</u>		
	1. <u>Thiazide diuretics</u>		
	a. Bendroflumethiazide (Naturetin)	mg	20420
	b. Benzthiazide (Aquatag)	mg	20430
	c. Chlorothiazide (Diuril)	mg	20440
	d. Chlorthalidone (Hygroton)	mg	20450
	e. Hydrochlorothiazide	mg	20460
	f. Metolazone (Zaroxolyn)	mg	20470
	2. <u>Loop Diuretics</u>		
	a. Bumetanide (Bumex)	mg	20480
	b. Ethacrynic Acid (Edecrin)	mg	20490
	c. Furosemide (Lasix)	mg	20500
	3. <u>Potassium Sparing Diuretic</u>		
	a. Amiloride (Midamor)	mg	20510
	b. Amiloride and Hydrochlorothiazide (Moduretic)	mg	20520
	c. Spironolactone (Aldactone)	mg	20530
	d. Spironolactone and Hydrochlorothiazide (Aldactazide)	mg	20540
	e. Triamterene (Dyrenium)	mg	20550
	f. Triamterene and Hydrochlorothiazide (Dyazide, Maxzide)	mg	20560

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4.	<u>Other Diuretics</u>		
	a. Indapamide (Lozol)	mg	20561
	b. Other	mg	20562
H.	<u>Lipid Lowering Agents</u>		
1.	Cholestyramine Resin (Questran)	grams	20570
2.	Clofibrate (Atromid-S)	mg	20580
3.	Colestipol Hydrochloride (Colestid)	grams	20590
4.	Dextrothyroxine Sodium (Choloxin)	mg	20600
5.	Gemfibrozil (Lopid)	mg	20610
6.	Niacin (Nicotinx)	mg	20620
7.	Probucol (Lorelco)	mg	20630
8.	Lovastatin (Mevacor)	mg	20631
9.	Pravastatin	mg	20632
10.	Simvastatin (Zocor)	mg	20633
I.	<u>Other Cardiovascular Drugs</u>	mg	20640
IV.	BLOOD FORMATION AND COAGULATION		
A.	<u>Antianemic Drugs</u>		
1.	Ferrous Fumarate	mg	30010
2.	Ferrous Gluconate (Fergon)	mg	30020
3.	Ferrous Sulfate	mg	30030
4.	Polysaccharide - Iron Complex (Hytinic or Niferex)	mg	30040
5.	Soy Protein - Iron Complex		30050
6.	Erythropoietin	units	30051
7.	Chromagen	mg	30052
B.	<u>Coagulants and Anticoagulants</u>		
1.	Dicumarol	mg	30060
2.	Warfarin (coumadin)	mg	30070
3.	Aminocaproic Acid (Amicar)	grams	30080
4.	Dipyridamole (persantine)	mg	30090
C.	<u>Other Blood Formation and Coagulation</u>	mg	30100
1.	Pentoxifylline (Trental)	mg	30110
V.	CENTRAL NERVOUS SYSTEM AGENTS		
A.	<u>Opiate Agonists</u>		
1.	Codeine	mg	40010
2.	Hydrocodone Bitartrate	mg	40020
3.	Hydromorphone Hydrochloride (Dilaudid)	mg	40030
4.	Levorphanol Tartrate (Levo-Dromoran)	mg	40040
5.	Meperidine Hydrochloride	mg	40050
6.	Morphine Sulfate (Roxanol 100)	mg	40060
7.	Oxycodone	mg	40070
8.	Propoxyphene Hydrochloride (Darvon)	mg	40080
9.	Pentazocine Hydrochloride and Aspirin (Talwin)	mg	40090

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B.	<u>Anticonvulsants</u>		
1.	Phenobarbital (Solfoton)	mg	40100
2.	Primidone (Mysoline)	mg	40110
3.	Clonazepam (Clonopin)	mg	40120
4.	Mephenytoin (Mesantoin)	mg	40130
5.	Phenytoin Sodium (Dilantin)	mg	40140
6.	Carbamazepine (Tegretol)	mg	40150
7.	Valproate Sodium (Depakene)	mg	40160
C.	<u>Antidepressants</u>		
1.	Phenelzine Sulfate (Nardil)	mg	40170
2.	Tranlycypromine Sulfate (Parnate)	mg	40180
3.	Amitriptyline Hydrochloride (Elavil)	mg	40190
4.	Desipramine Hydrochloride (Pertofrane)	mg	40200
5.	Doxepin Hydrochloride (Sinequan)	mg	40210
6.	Imipramine Hydrochloride (Tofranil)	mg	40220
7.	Nortriptyline Hydrochloride (Aventyl) (Pamelor)	mg	40230
8.	Trazodone Hcl (Desyrel)	mg	40231
9.	Fluoxetine Hcl (Prozac)	mg	40232
D.	<u>Tranquilizers and Antipsychotics</u>		
1.	Chlorpromazine (Thorazine)	mg	40240
2.	Perphenazine (Trilafon)	mg	40250
3.	Prochloroperazine (Compazine)	mg	40260
4.	Thioridazine (Mellaril)	mg	40270
5.	Trifluoperazine Hydrochloride (Stelazine)	mg	40280
6.	Haloperidol (Haldol)	mg	40290
E.	<u>Anxiolytics, Sedatives and Hypnotics</u>		
1.	Alprazolam (Xanax)	mg	40300
2.	Chlordiazepoxide Hydrochloride (Librium)	mg	40310
3.	Diazepam (Valium)	mg	40320
4.	Flurazepam (Dalmane)	mg	40330
5.	Lorazepam (Antivan)	mg	40340
6.	Oxazepam (Serax)	mg	40350
7.	Chloral Hydrate	mg	40360
8.	Glutethimide (Doriden)	mg	40370
9.	Hydroxyzine Hydrochloride (Atarax)	mg	40380
10.	Triazolam (Halcion)	mg	40390
11.	Fiorinol	mg	40391
12.	Restoril	mg	40392
F.	<u>Anti Manic Agents</u>		
1.	Lithium Carbonate	mg	40400
G.	<u>Antiparkinsonian Agents</u>		
1.	Benzotropine Mesylate (Cogentin)	mg	40410
2.	Carbidopa (Lodosyn)	mg	40420
3.	Levodopa (Dopar)	mg	40430
4.	Levodopa and Carbidopa (Sinemet)	mg	40440

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H.	<u>Other Central Nervous System Agents</u>	mg	40450
1.	Oxybutynin Chloride (Ditropan)	mg	40451
2.	Cyclobenzaprine Hcl. (Flexeril)	mg	40452
3.	Darvocet	mg	40453
4.	Percocet	mg	40454
5.	Dicyclomine Hcl.	mg	40455
6.	Donnatal Extentabs	tablets	40456
VI.	<u>ELECTROLYTES, VITAMINS, MINERALS</u>		
A.	<u>Alkalinizing Agents</u>		
1.	Sodium Bicarbonate	mg	50010
2.	Sodium Citrate (Polycitra Bicitra)	mg	50020
B.	<u>Ammonia Detoxicants</u>		
1.	Lactulose	grams	50030
C.	<u>Electrolytes</u>		
1.	Calcium Carbonate (Study and Other)	mg	50040
2.	Calcium Gluconate	mg-gram	50050
3.	Potassium Chloride (K-lor and others)	mEq	50060
4.	Sodium Polystyrene Sulfonate (Kayexalate)	grams	50070
5.	Calcium Citrate (Citrical)	mg	50071
6.	Urocit K	mEq	50072
7.	Calcium Acetate (Phoslo)	mg	50073
8.	Calcium Chloride	mg	50074
D.	<u>Uricosuric Agents</u>		
1.	Probenecid (Benemid)	mg	50080
2.	Sulfinpyrazone (Anturane)	mg	50090
E.	<u>Vitamins</u>		
1.	Study Multivitamin	tablet	50100
2.	Other Multivitamin	tablet	50110
3.	Vitamin A	units	50120
4.	Vitamin B Complex	tablet	50130
5.	Ascorbic Acid	mg	50140
6.	Calcifediol	ug	50150
7.	Calcitriol (Rocaltrol)	ug	50160
8.	Dihydrotachysterol	mg	50170
9.	Ergocalciferol	units	50180
10.	Vitamin E	units	50190
11.	Vitamin K	mg	50200
12.	Folic Acid	mg	50201
13.	Phos-Ex	mg	50202
14.	Pyridoxine (Vitamine B6)	mg	50203
F.	<u>Fish Oils</u>		
1.	Pro Mega	mg	50210
2.	Max Epa	mg	50220
3.	Proto Chol	mg	50230

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G.	<u>Other</u>	mg	50240
	1. Magnesium Chloride	mEq	50241
	2. Ipratropium Bromide (Atrovent) (Inhalent)	mcG	50242
VII.	GASTROINTESTINAL DRUGS		
A.	<u>Antacids</u>		
	1. Aluminum Carbonate/no magnesium	mg/tabs	60010
	2. Aluminum Hydroxide/no magnesium	mg/tabs	60020
	3. Aluminum Phosphate (Phosphaljel)	mg	60030
	4. Magnesium containing antacids	mg	60040
B.	<u>Antidiarrheal Agents</u>		
	1. Diphenoxylate Hydrochloride with Atropine (Lomotil)	mg	60050
	2. Kaolin and Pectin (Kaopectate)	ml	60060
	3. Loperamide Hydrochloride (Imodium)	mg	60070
	4. Opium Preparation		60080
C.	<u>Laxatives (Other)</u>	mg	60085
	1. Peri-colace	mg	60084
	2. Metamucil	gram	60086
	3. Enulose	mg	60087
	4. Colace	mg	60088
	5. Senokot (liquid)	mg	60089
D.	<u>Cholelitholytic Agents</u>		
	1. Chenodiol (Chenix)	mg	60090
E.	<u>Digestants</u>		
	1. Glutamic acid Hydrochloride (Acidulin)	mg	60100
	2. Pancreatin	units	60110
	3. Pancrelipase	units	60120
F.	<u>Anti Emetics</u>		
	1. Prochlorperazine (Compazine)	mg	60130
	2. Thiethylperazine (Torecon)	mg	60140
	3. Trimethobenzamide Hydrochloride (Tigan)	mg	60150
	4. Meclizine Hydrochloride (Antivert)	mg	60160
G.	<u>Peptic Ulcer Therapy</u>		
	1. Cimetidine (Tagamet)	mg	60170
	2. Ranitidine (Zantac)	mg	60180
	3. Sucralfate (Carafate)	grams	60190
	4. Famotidine (Pepcid)	mg	60191
	5. Nizatidine (Axid)	mg	60192
H.	<u>Stool Softeners</u>	mg	60200
	1. Magnesium Oxide	mg	60210
	2. Mylicon	mg	60220
I.	<u>Antisecretary Agents</u>		
	1. Omeprazole (Prilosec)	mg	60400

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J.	<u>Other Gastrointestinal Drugs</u>		60600
1.	Reglan	mg	60610
VIII.	<u>HORMONES AND SYNTHETIC SUBSTITUTES</u>		
A.	<u>Adrenal Hormones</u>		
1.	Beclomethasone Dipropionate	Aerosol	70010
2.	Cortisone Acetate	mg	70020
3.	Dexamethasone	mg	70030
4.	Fludrocortisone Acetate (Florinef)	mg	70040
5.	Hydrocortisone (Cortef)	mg	70050
6.	Methylprednisolone (Medrol)	mg	70060
7.	Prednisolone	mg	70070
8.	Prednisone	mg	70080
9.	Triamcinolone (Aristocort)	mg	70090
10.	Predforte (Eye Drops)	drops	70095
B.	<u>Androgens</u>		
1.	Danazol (Danocrine)	mg	70100
2.	Fluoxymesterone (Halotestin)	mg	70110
3.	Methyltestosterone (Android)	mg	70120
C.	<u>Contraceptives</u>		
1.	Ethinyl Estradiol Combinations	mg	70130
2.	Norethindrone (Micronor)	mg	70140
3.	Norgestrel (Ovrette)	mg	70150
D.	<u>Estrogens</u>		
1.	Chlorotrianisene (Tace)	mg	70160
2.	Dienestrol (Estraguard)	cream	70170
3.	Diethylstilbestrol	mg	70180
4.	Estradiol (Estrace)	mg	70190
5.	Conjugated Estrogens (Premarin)	mg	70200
6.	Estropipate (Ogen)	mg	70210
7.	Esterified Estrogens (estratal)	mg	70220
E.	<u>Antidiabetic Agents</u>		
1.	Insulin preparations	units	70230
2.	Acetohexamide (Dymelor)	mg	70240
3.	Chlorpropamide (Diabenese)	mg	70250
4.	Glipizide (Glucotrol)	mg	70260
5.	Glyburide (Dia Beta)	mg	70270
6.	Tolazamide (Ronase)	mg	70280
7.	Tolbutamide (Orinase)	mg	70290
F.	<u>Pituitary Substitutes</u>		
1.	Desmopressin Acetate nasal spray (DDAVP)	ug	70300
2.	Lypressin (Diapid) nasal spray	ug	70310
G.	<u>Progestins</u>		
1.	Medroxyprogesterone Acetate (Provera)	mg	70320

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H.	<u>Thyroid Agents and Antithyroid Drugs</u>		
1.	Levothyroxine Sodium (Synthroid)	mg	70330
2.	Liothyronine Sodium (Cytamel)	ug	70340
3.	Thyroglobulin (Proloid)	mg	70350
4.	Thyroid (Armour)	mg	70360
5.	Methimazole (Tapazole)	mg	70370
6.	Propylthiouracil	mg	70380
I.	<u>Other Hormones</u>	mg	70390
IX.	<u>AGENTS USED FOR RESPIRATORY DISORDERS</u>		
A.	<u>Agents used in Asthma</u>		
1.	Aminophylline and Theophylline preparations	mg	80010
2.	Cromolyn Sodium (inhalation therapy)	inhalant	80020
3.	Albuterol (Proventil, Ventolin)	inhalant	80030
4.	Bitolterol Mesylate (Tornalate)	inhalant	80040
5.	Ephedrine	mg	80050
6.	Isoetharine Mesylate (Bronkosol)	inhalant	80060
7.	Isoproterenol Hydrochloride (Isuprel)	inhalant	80070
8.	Metaproterenol Sulfate (Alupent)	inhalant	80080
9.	Terbutaline Sulfate (Brethine)	mg/inhalant	80090
B.	<u>Other (antihistamines)</u>	mg	80100
1.	Dimetane	mg	80101
2.	Astemizole (Hismanal)	mg	80102
3.	Terfenadine (Seldane)	mg	80104
4.	CONTAC	mg	80105
5.	Chlorpheniramine Maleate (Teldron)	mg	80106
6.	Diphenhydramine Hydrochloride (Benedryl)	mg	80107
7.	Tylenol Cold	tablet	80108
C.	<u>Decongestants</u>		
1.	Pseudoephedrine Hydrochloride (Sudafed)	mg	80200
2.	Entex IA	tablet	80210
X.	<u>Immunosuppressants</u>		
A.	Cyclosporine	mg	80500
B.	OKT3	mg	80501
XI.	<u>MISCELLANEOUS</u>		
A.	Allopurinol (Lopurin)	mg	90010
1.	Oxypurinol	mg	90011
B.	Colchicine	mg	90020
C.	Disulfiram (Antabuse)	mg	90030
D.	<u>Non Steroidal Anti-Inflammatory Agents</u>		
1.	Aspirin (many brand names)	mg	90040
2.	Diffunisal (Dolobid)	mg	90050
3.	Fenoprofen Calcium (Nalfon)	mg	90060
4.	Ibuprofen (Advil, Motrin)	mg	90070
5.	Indomethacin (Indocin)	mg	90080
6.	Melofenamate Sodium (Meclomen)	mg	90090
7.	Mefenamic Acid (Ponstel)	mg	90100
8.	Naproxen Sodium (Naprosyn)	mg	90110
9.	Oxyphenbutazone and Phenylbutazone	mg	90120

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	10.	Piroxicam (Feldene)	mg	90130
	11.	Sulindac (Clinoril)	mg	90140
	12.	Tolmetin Sodium (Tolectin)	mg	90150
	13.	Voltaren	mg	90151
	14.	Salsalate	mg	90152
	15.	Cytotec (Misoprostol)	mcg	90153
	16.	Flavoxate Hcl. (Urispas)	mg	90154
	17.	Trilisate	mg	90155
E.		<u>Miscellaneous Analgesics and Antipyretics</u>		
	1.	Acetaminophen	mg	90160
	2.	Midrim	capsule	90161
F.		<u>Other</u>	mg	90170
	3.	Gama Globulin	grams	90171
G.		<u>Cancer Treatments</u>		
	1.	Chemotherapy of any kind	any	90180
	2.	Radiation of any kind	any	90190
H.		<u>Agents for Glaucoma</u>		
	1.	Pilocarpine (eye drops)	drops	90200
	2.	Levobunolol Hcl. (Betagan)	drops	90201
	3.	Timolol Maleate (Timoptic)	drops	90202
	4.	E-Pilo	drops	90203

Alphabetical List of MDRD Drugs

Acebutolol (Sectral)	20142
Acetaminophen - mg	90160
Acetohexamide - mg	70240
Acidulin - mg	60100
Acyclovir Sodium - mg	00390
Advil - mg	90070
Albuterol - inhalant	80030
Aldactazide - mg	20540
Aldomet - mg	20190
Alkeran - mg	10080
Allopurinol - mg	90010
Alprazolam - mg	40300
Alseroxylon - mg	20250
Altace - mg	20333
Aluminum Carbonate/no magnesium - mg/tabs	60010
Aluminum Hydroxide/no magnesium - mg/tabs	60020
Aluminum Phosphate - mg	60030
Alupent - inhalant	80080
Amantadine Hydrochloride - mg	00400
Amicar - grams	30080
Amiloride - mg	20510
Amiloride & Hydrochlorothiazide - mg	20520
Aminocaproic Acid - grams	30080
Aminophylline & Theophylline preparations - mg	80010
Amiodarone - mg	20072
Amitriptyline Hydrochloride - mg	40190
Amoxicillin - mg	00230
Amoxicillin & Calvulanate Potassium - mg	00240
Ampicillin - mg	00250
Anabrine - mg	00050
Android - mg	70120
Anspor - mg	00130
Antabuse - mg	90030
Antepar - mg	00030
Antivan - mg	40340
Antivert - mg	60160
Anturane - mg	50090
Apresoline - mg	20350
Aquatag - mg	20430
Aristocort - mg	70090
Armour - mg	70360
Ascorbic Acid - mg	50140
Aspirin (many brand names) - mg	90040
Astemizole - mg	80102
Atarax - mg	40380
Atrovent - mcg	50242
Augmentin - mg	00240

Aventyl - mg	40230
AXID - mg	60192
Aygroton - mg	20450
Azathioprine - mg	10010
Bactrim - mg	00380
Beclomethasone Dipropionate - Aerosol	70010
Bendroflumethiazide - mg	20420
Benedryl - mg	80107
Benemid - mg	50080
Benzthiazide - mg	20430
Benztropine Mesylate - mg	40410
Betagan - drops	90201
Betaxolol Hcl - mg	20141
Bicillin - units	00160
Biltricide - mg	00040
Bitolterol Mesylate - inhalant	80040
Blocadren - mg	20140
Brethine - mg/inhalant	80090
Bronkosol - inhalant	80060
Bumetanide - mg	20480
Bumex - mg	20480
Busulfan - mg1	10020
Calan - mg	20170
Calcifediol - ug	50150
Calcitriol - ug	50160
Calcium Acetate - mg	50073
Calcium Carbonate (Study and Other) - mg	50040
Calcium Chloride - mg	50074
Calcium Citrate - mg	50071
Calcium Gluconate - mg-gram	50050
Capoten - mg	20320
Captopril - mg	20320
Carafate - gram	60190
Carbamazepine - mg	40150
Carbenicillin Indanyl Sodium - mg	00260
Carbidopa - mg	40420
Cardiazem - mg	20150
Cardilate - mg	20380
Cardioquin - mg	20060
Catapres - mg	20180
Ceclor - mg	00100
CeeNu - mg	10060
Cefaclor - mg	00100
Cefadroxil - mg	00110
Cephalexin - mg	00120
Cephradine - mg	00130
Chemotherapy of any kind	90180
Chenix - mg	60090
Chenodiol - mg	60090
Chloral Hydrate - mg	40360
Chlorambucil - mg	10030
Chloramphenicol - mg	00140
Chlordiazepoxide Hydrochloride - mg	40310

Chloromycetin - mg	00140
Chloroquine Hydrochloride - mg	00410
Chlorothiazide - mg	20440
Chlorotrianisene - mg	70160
Chlorpheniramine Meleate - mg	80106
Chlorpromazine - mg	40240
Chlorpropamide - mg	70250
Chlorthalidone - mg	20450
Cholestyramine Resin - gram	20570
Choloxin - mg	20600
Chromagen - mg	30052
Cimetidine - mg	60170
Ciprofloxacin - gram	00460
Cleocin - mg	00310
Clindamycin Hydrochloride - mg	00310
Clinoril - mg	90140
Clofibrate - mg	20580
Clonazepam - mg	40120
Clonidine - mg	20180
Clonopin - mg	40120
Cloxacillin Sodium - mg	00190
Cloxapen - mg	00190
Codeine - mg	40010
Cogentin - mg	40410
Colace - mg	60088
Colchicine - mg	90020
Colestipol Hydrochloride - grams	20590
Compazine - mg	40260
Conjugated Estrogens - mg	70200
CONTAC - mg	80105
Corgard - mg	20110
Cortef - mg	70050
Cortisone Acetate - mg	70020
Co-trimoxazole - mg	00380
Coumadin - mg	30070
Cromolyn Sodium (inhalation therapy) - inhalant	80020
Crystodigin - mg	20010
Cyclobenzaprine Hcl. - mg	40452
Cyclophosphamide - mg	10040
Cyclosporine - mg	80500
Cytomel - ug	70340
Cytotec - mcg	90153
Cytosan - mg	10040
Dalmane - mg	40330
Danazol - mg	70100
Danocrine - mg	70100
Daraprim - mg	00430
Darvocet - mg	40453
Darvon - mg	40080
DDAVP - ug	70300
Declomycin - mg	00270

Demeclocycline Hydrochloride - mg	00270
Depakene - mg	40160
Deserpidine - mg	20240
Desipramine Hydrochloride - mg	40200
Desmopressin Acetate nasal spray - ug	70300
Desyrel - mg	40231
Dexamethasone - mg	70030
Dextrothyroxine Sodium - mg	20600
Diabenese - mg	70250
Dia Beta - mg	70270
Diapid - ug	70310
Diazepam - mg	40320
Diazoxide - mg	20340
Dicloxacillin Sodium - mg	00200
Dicumarol - mg	30060
Dicyclomine Hcl. - mg	40455
Dienestrol - cream	70170
Diethylstilbestrol - mg	70180
Diflunisal - mg	90050
Digitalis - mg	20020
Digitoxin - mg	20010
Digoxin - mg	20030
Dihydrotachysterol - mg	50170
Dilantin - mg	40140
Dilaudid - mg	40030
Diltiazem Hydrochloride - mg	20150
Dimetane - mg	80101
Diphenhydramine Hydrochloride - mg	80107
Diphenoxylate Hydrochloride w/Atropine - mg	60050
Dipyridamole (Persantine) - mg	30090
Disopyramide Phosphate - mg	20040
Disulfiram - mg	90030
Ditropan - mg	40451
Diuril - mg	20440
Dolobid - mg	90050
Donnatal Extentabs - tablet	40456
Dopar - mg	40430
Doriden - mg	40370
Doxazosin Mesylate (Cardura) - mg	20372
Doxepin Hydrochloride - mg	40210
Doxycycline Calcium - mg	00280
Duotrate - mg	20410
Duricef - mg	00110
Dyazide - mg	20560
Dymelor - mg	70240
Dynapen - mg	00200
Dyrenium - mg	20550
Edecrin - mg	20490
Elavil - mg	40190

Emetine Hydrochloride - mg	00010
Enalapril - mg	20330
Encainide - mg	20071
Entex LA - tablet	80210
Ephedrine - mg	80050
E-Pilo - drops	90203
Ergocalciferol - units	50180
Erythryl Tetranitrate - mg	20380
Erythromycin - mg	00150
Erythropoietin - units	30051
Esidrix - mg	20220
Esterified Strogens - mg	70220
Estrace - mg	70190
Estradiol - mg	70190
Estraguard - cream	70170
Estratal - mg	70220
Estropipate - mg	70210
Ethacrynic Acid - mg	20490
Ethambutol - mg	00330
Ethinyl Estradiol Combinations - mg	70130
Eutonyl - mg	20310
Famotidine - mg	60191
Feldene - mg	90130
Felodipine - mg	20173
Fenoprofen Calcium - mg	90060
Fergon - mg	30020
Ferrous Fumarate - mg	30010
Ferrous Gluconate - mg	30020
Ferrous Sulfate - ?	30030
Fiorinol - mg	40391
Flagyl - mg	00020
Flavoxate Hcl - mg	90154
Florinef - mg	70040
Fludrocortisone Acetate - mg	70040
Fluoxetine Hcl - mg	40232
Fluoxymesterone - mg	70110
Flurazepam - mg	40330
Folic Acid	50201
Furosemide - mg	20500
Gantricin - grams	00383
Gemfibrozil - mg	20610
Geocillin - mg	00260
Glipizide - mg	70260
Glucotrol - mg	70260
Glutamic acid Hydrochloride - mg	60100
Glutethimide - mg	40370
Glyburide - mg	70270
Griseofulvin - mg	00070
Guanabenz Acetate - mg	20200

Guanadrel Sulfate - mg	20280
Guanethidine Monosulfate - mg	20290
Halcion - mg	40390
Haldol - mg	40290
Haloperidol - mg	40290
Haltestin - mg	70110
Harmonyl - mg	20240
Hismanal - mg	80102
Hiwolfia - mg	20270
Hydralazine - mg	20350
Hydrea - mg	10050
Hydrochlorothiazide - mg	20460
Hydrocodone Bitartrate - mg	40020
Hydrocortisone - mg	70050
Hydromorphone Hydrochloride - mg	40030
Hydroxyurea - mg	10050
Hydroxyzine Hydrochloride - mg	40380
Hylorel - mg	20280
Hytinic - mg	30040
Hytrin - mg	20371
Ibuprofen - mg	90070
Imipramine Hydrochloride - mg	40220
Immuran - mg	10010
Imodium - mg	60070
Inderal - mg	20130
Indocin - mg	90080
Indomethacin - mg	90080
Insulin preparations - mg	70230
Inversine - mg	20300
Ipratropium Bromide	50242
Ismelin - mg	20290
Isoetharine Mesylate - inhalant	80060
Isoniazid - mg	00340
Isoproterenol Hydrochloride - inhalant	80070
Isoptin - mg	20170
Isordil - mg	20390
Isosorbide Dinitrate - mg	20390
Isoxsuprine - mg	20373
Isradipine - mg	20172
Isuprel - inhalant	80070
Kaolin and Pectin - ml	60060
Kaopectate - ml	60060
Kayexalate - gram	50070
Keflex - mg	00110
Ketoconazole - mg	00080
Labetalol Hydrochloride - mg	20090
Lactulose - grams	50030
Lanoxicaps - mg	20030

Lasix - mg	20500
Laxatives (any) - ?	60085
Leukeran - mg	10030
Levatol - mg	20143
Levobunolol Hcl. - drops	90201
Levodopa - mg	40430
Levodopa & Carbidopa - mg	40440
Levo-Dromoran - mg	40040
Levorphanol Tartrate - mg	40040
Levothyroxine Sodium - mg	70330
Librium - mg	40310
Liothyronine Sodium - ug	70340
Lithium Carbonate - mg	40400
Lomotil - mg	60050
Lomustine - mg	10060
Loniten - mg	20360
Loperamide Hydrochloride - mg	60070
Lopid - mg	20610
Lopurin - mg	90010
Lorazepam - mg	40340
Loxelco - mg	20630
Lorpessor - mg	20100
Lovastatin - mg	20631
Lozol - mg	20561
Lypressin nasal spray - ug	70310
Lysodren - mg	10110
Macrochantin - mg	00360
Magnesium containing antacids - mg	60040
Magnesium Chloride	50241
Magnesium Oxide - mg	60210
Matulane - mg	10130
Max EPA - mg	50220
Mecamylamine Hydrochloride - mg	20300
Meclizine Hydrochloride - mg	60160
Meclomen - mg	90090
Medofenamate Sodium - mg	90090
Medrol - mg	70060
Medroxyprogesterone Acetate - mg	70320
Mefenamic Acid - mg	90100
Megace - mg	10070
Megestrol Acetate - mg	10070
Mellaril-S - mg	40270
Melphalan - mg	10080
Meperidine Hydrochloride - mg	40050
Mephenytoin - mg	40130
Mercaptopurine - mg	10090
Mesantoin - mg	40130
Metamucil - gram	60086
Metaproterenol Sulfate - inhalant	80080

Methimazole - mg	70370
Methotrexate - mg	10100
Methyldopa - mg	20190
Methylprednisolone - mg	70060
Methyltestosterone - mg	70120
Metolazone - mg	20470
Metoprolol Tartrate - mg	20100
Metronidazole - mg	00020
Micronor - mg	70140
Midamor - mg	20510
Midrim - capsule	90161
Minipress - mg	20370
Minoxidil - mg	20360
Minoxidil - Topical - ml	20361
Mintezol - mg	00060
Misoprostol - mcg	90153
Mitotane - mg	10110
Moderil - mg	20260
Moduretic - mg	20520
Morphine Sulfate - mg	40060
Motrin - mg	90070
Myambutol - mg	00330
Mycostatin - units	00090
Myleran - mg	10020
Mylicon - mg	60220
Mysoline - mg	40110
Nadolol - mg	20110
Nafcillin Sodium - mg	00210
Naldixic Acid - mg	00355
Nalfon - mg	90060
Naprosyn - mg	90110
Naproxen Sodium - mg	90110
Nardil - mg	40170
Naturetin - mg	20420
Niacin - mg	20620
Nicardipene (Cardene)	20171
Nicotinex - mg	20620
Nifedipine - mg	20160
Niferex - mg	30040
Nitrofurantoin - mg	00360
Nitroglycerin - sublingual, paste, and patch	20400
Nizatidine (Axid) - mg	60192
Nizoral - mg	00080
Nolvadex - mg	10140
Norethindrone - mg	70140
Norfloxacin	00470
Norgestrel - mg	70150
Normodyne - mg	20090

Noroxin - mg	00470
Norpace - mg	20040
Nortriptyline Hydrochloride - mg	40230
Nystatin - cc	00091
Nystatin - units	00090
Ogen - mg	70210
OKT3 - mg	80501
Omeprazole - mg	60400
Opium Preparation - ?	60080
Orinase - mg	70290
Other - mg	10180
Other - mg	50240
Other - mg	80100
Other - mg	90170
Other ACE Inhibitors - mg	20332
Other Antibiotic - mg	00450
Other Blood Coagulants Anticoagulants - mg	30100
Other Cardiovascular Drugs - mg	20640
Other Central Nervious System Agents - mg	40450
Other Diuretics - mg	20562
Other Gastrointestinal Drugs - mg	60200
Other Hormones - mg	70390
Other Multivitamin - pill	50110
Ovrette - mg	70150
Oxacillin Sodium - mg	00220
Oxazepam - mg	40350
Oxybutynin Chloride - mg	40451
Oxycodone - mg	40070
Oxyphenbutazone & Penylbutazone - mg	90120
Oxypurinol - mg	90011
Oxytetracycline Hydrochloride - mg	00290
Pamelor - mg	40230
Pancreatin - units	60110
Pancrelipase - units	60120
Pargyline Hydrochloride - mg	20310
Parnate - mg	40180
Penbutolol - mg	20143
Penicillin G Benzathine - units	00160
Penicillin G Potassium - units	00170
Penicillin V Potassium - mg	00180
Pentaerythritol tetranitrate - mg	20410
Pentazocine Hydrochloride and Aspirin - mg	40090
Pentids - units	00170
Pentoxifylline - mg	30110
Pepcid (Famotidine) - mg	60191
Percocet - mg	40454
Peri-Colace - mg	60084
Perphenazine - mg	40250
Persantine - mg	30090

Pertofrane - mg	40200
Phenelzine Sulfate - mg	40170
Phenobarbital - mg	40100
Phenytoin Sodium - mg	40140
Phos-Ex - mg	50202
Phoslo - mg	50073
Phosphaljel - mg	60030
Pilocarpine (eye drop) - drops	90200
Pindolol - mg	20120
Piperazine Citrate - mg	00030
Pipobroman - mg	10120
Piroxicam - mg	90130
Plendil - mg	20173
Polycitra - ml	50020
Polysaccharide - Iron Complex - mg	30040
Ponstel - mg	90100
Potassium Chloride (K-lor and others) - mEq	50060
Praziquantel - mg	00040
Prazosin Hydrochloride - mg	20370
Predforte - drops	70095
Prednisolone - mg	70070
Prednisone - mg	70080
Premarin - mg	70200
Prilosec - mg	60400
Primaquine Phosphate - mg	00420
Primidone - mg	40110
Probenecid - mg	50080
Probucol - mg	20630
Procainamide Hydrochloride - mg	20050
Procan - mg	20050
Procarbazine Hydrochloride - mg	10130
Procardia - mg	20160
Prochloroperazine - mg	40260
Prochlorperazine - mg	60130
Proglycem - mg	20340
Proloid - mg	70350
Pro Mega - mg	50210
Propoxyphene Hydrochloride - mg	40080
Propranolol Hydrochloride - mg	20130
Propylthiouracil - mg	70380
Prostaphlin - mg	00220
Proto Chul - mg	50230
Provastatin - mg	20632
Proventil - inhalant	80030
Provera - mg	70320
Prozac - mg	40232
Pseudoephedrine Hydrochloride - mg	80200
Purinethol - mg	10090

Pyrimethamine - mg	00430
Pyridoxin - mg	50203
Questran - gram	20570
Quinacrine Hydrochloride - mg	00050
Quinidine Gluconate - mg	20060
Quinight - mg	20060
Quinine Sulfate - mg	00440
Radiation of any kind	90190
Ramipril - mg	20333
Ranitidine - mg	60180
Rauwiloid - mg	20250
Rauwolfia Serpentina - mg	20270
Reglan - mg	60610
Regroton - mg	20230
Rescinnamine - mg	20260
Reserpine - mg	20210
Reserpine & Chlorthalidone - mg	20230
Reserpine & Hydrochlorothiazide - mg	20220
Restoril - mg	40392
Rifadin - g	00350
Rifampin - g	00350
Ronase - mg	70280
Roxanol 100 - mg	40060
Salsalate - mg	90152
Senokot (liquid) - mg	60089
Serox - mg	40350
Serpalan - mg	20210
Simvastatin - mg	20633
Sinemet - mg	40440
Sinequan - mg	40210
Sodium Bicarbonate - mg	50010
Sodium Citrate - mg	50020
Sodium Polystyrene Sulfonate - gram	50070
Solfoton - mg	40100
Soy Protein - Iron Complex - ?	30050
Spironolactone - mg	20530
Spironolactone & Hydrochlorothiazide - mg	20540
Stelazine - mg	40280
Study Multivitamin - pill	50100
Sucralfate - gram	60190
Sulfasalazine - gram	00382
Sulfinpyrazone - mg	50090
Sulfisoxazole - grams	00383
Sulindac - mg	90140
Symmetrel - mg	00400
Synthroid - mg	70330
Tace - mg	70160
Tagamet - mg	60170
Talwin - mg	40090
Tamoxifen Citrate - mg	10140
Tapazole - mg	70370
Tegretol - mg	40150

Tenex (Guanfacine Hydrochloride) - mg	20376
Tenormin - mg	20080
Tenoretic - mg	20201
Terazocin - mg	20371
Terbutaline Sulfate - mg/inhalant	80090
Terramycin - mg	00290
Teslac - mg	10150
Testolactone - mg	10150
Tetracycline - mg	00300
Thiabenadazole - mg	00060
Thiethylperazine - mg	60140
Thioguanine - mg	10160
Thioridazine - mg	40270
Thorazine - mg	40240
Thyroglobulin - mg	70350
Thyroid - mg	70360
Tigan - mg	60150
Timolol Maleate - mg	20140
Timolol Maleate - drops	90202
Timoptic - drops	90202
Tocainide Hydrochloride - mg	20070
Tofranil - mg	40220
Tolazamide - mg	70290
Tolbutamide - mg	70290
Tolectin - mg	90150
Tolmetin Sodium - mg	90150
Tonocard - mg	20070
Torecon - mg	60140
Tornalate - inhalant	80040
Tranlycypromine Sulfate - mg	40180
Trazodone Hcl - mg	40231
Trental - mg	30090
Triamcinlone - mg	70090
Triamterene - mg	20550
Triamteren & Hydrochlorothiazide - mg	20560
Triazdam - mg	40390
Trifluoperazine Hydrochloride - mg	40280
Trilafon - mg	40250
Trilisate - mg	90155
Trimethoprim - mg	00370
Trimethylperazine Hydrochloride - mg	60150
Tylenol Cold - tablet	80108
Unipen - mg	00210
Uracil Mustard - mg	10170
Urispas - mg	90154
Urocit K - mEq	50072
Valium - mg	40320
Valproate Sodium - mg	40160
Vancocin - mg	00220
Vancomycin - mg	00320
Vasotec - mg	20330
Ventolin - inhalant	80030
Verapamil Hydrochloride - mg	20170
Vercyte - mg	10120

Vibramycin - mg	00280
Visken - mg	20120
Vitamin A - units	50120
Vitamin B Complex - tablet	50130
Vitamin B6 - mg	50203
Vitamin E - units	50190
Vitamin K - mg	50200
Voltaren - mg	90151
Warfarin - mg	30070
Wytensin - mg	20200
Xanax - mg	40300
Zantac - mg	60180
Zaroxolyn - mg	20470
Zestril - mg	20331
Zocor - mg	20633
Zovirax - mg	00390

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Form # 04
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Modification of Diet in Renal Disease Study Demographic and Baseline Examination Form

This form is to be completed by the study team at the patient's first clinic visit during baseline.

FORM # 0 4

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date Primary Informed Consent Form was signed..... / /
b. Has a copy of the consent form been sent to the DCC? (1 = yes, 2 = no)
5. a. Date of Patient Visit..... / /
b. Visit Type B
c. Visit Number..... 0 0 0
6. Referral Source

1 = Self	5 = Other (20 characters maximum)
2 = Friend	()
3 = Outside doctor	9 = Unknown
4 = Study doctor	
7. Has the name and address of a contact person who may know the whereabouts of the patient been recorded? (1 = yes, 2 = no).....
8. Date of Birth / /
9. Sex

1 = Male
2 = Female, able to become pregnant
3 = Female, not able to become pregnant
10. Race/Population Group.....

1 = White	6 = Pacific Islander
2 = Black	7 = Other (20 characters maximum)
3 = Hispanic	()
4 = Asian	9 = Unknown
5 = Native American	
11. Education.....

1 = College graduate with professional training	5 = Completed 10-11 years of school
2 = College graduate	6 = Completed 7-9 years of school
3 = At least one year of college	7 = Completed <7 years of school
4 = High school graduate	9 = Unknown

Modification of Diet in Renal Disease Study Demographic and Baseline Examination Form

17. a. What is the total household gross yearly income? (Enter the code for the appropriate income category in the instructions.).....
- b. How many people are supported, in part or in whole, from the total household income?.....
18. a. Religion.....
- | | |
|----------------|-----------------------------------|
| 1 = Catholic | 4 = Other (20 characters maximum) |
| 2 = Protestant | (_____) |
| 3 = Jewish | 5 = None |
| | 9 = Unknown |
- b. Does the patient feel that his or her religious practices influence his or her diet? (1 = yes, 2 = no).....
- If yes, specify _____
19. Marital Status.....
- | | |
|---------------|--------------|
| 1 = Single | 4 = Divorced |
| 2 = Married | 5 = Widowed |
| 3 = Separated | 9 = Unknown |
20. Living Arrangements (1 = yes, 2 = no)
- a. alone.....
 - b. with spouse.....
 - c. with children.....
 - d. with parents.....
 - e. with other relatives.....
 - f. with friends.....

Documented Medical Problems (1 = yes, 2 = no)

- 21. Type II Diabetes.....
- 22. Coronary Artery Disease.....
- 23. Peptic Ulcer.....
- 24. Cancer.....
- 25. Cerebral Vascular Disease.....
- 26. Peripheral Vascular Disease.....
- 27. Hypertension.....
- 28. Hyperlipidemia.....
- 29. Major surgery in the past year.....

**Modification of Diet in Renal Disease Study
Demographic and Baseline Examination Form**

30. Other Medical Diagnoses (1 = yes, 2 = no)

Specify: (20 characters maximum)

Smoking History

31. How many packs per day does the patient smoke?.....

32. How many years has the patient been smoking cigarettes?.....

33. If the patient does not smoke cigarettes presently, did he or she ever smoke them?.....

- 1 = Regularly
- 2 = Occasionally
- 3 = Never (<20 packs in lifetime)

34. Does the patient currently smoke cigars or pipes?.....

- 1 = Yes
- 2 = No

Physical Examination

35. Date of physical exam..... / /

Complete Blood Pressure Form.

36. Eyes: fundoscopic finding (Keith Wagner-Barker Classification)

- | | |
|--------------|---------------|
| 0 = Normal | 3 = Grade III |
| 1 = Grade I | 4 = Grade IV |
| 2 = Grade II | 9 = Not done |

37. Edema.....

- | | |
|------------|--------------|
| 0 = Absent | 3 = 3+ |
| 1 = 1+ | 4 = 4+ |
| 2 = 2+ | 9 = Not done |

38. Standard Body Weight

a. height (cm) 1.).....

2.).....

b. elbow width (cm) 1.).....

2.).....

c. frame size.....

- 1 = Small
- 2 = Medium
- 3 = Large

d. body weight (kg) 1.).....

2.).....

Modification of Diet in Renal Disease Study Demographic and Baseline Examination Form

38. (Continued)
- e. standard weight (kg).....
 - f. percentage of standard weight (%).....
 - g. Is the percentage of standard weight outside the allowable range (80% - 160%)? (1 = yes, 2 = no).....
 - h. certification number of dietitian.....
 - i. weight status.....
 - 1 = Patient wants to lose weight
 - 2 = Patient wants to gain weight
 - 3 = Patient does not want weight change

Drugs/Nutritional Supplements

39. Referring to the Drug list in the Manual of Operations, list all drugs including nutritional supplements and over-the-counter medications the patient is currently taking. Pay careful attention to the units.

	Code Number	Dosage	Times/Day
a.	_____	_____	_____
b.	_____	_____	_____
c.	_____	_____	_____
d.	_____	_____	_____
e.	_____	_____	_____
f.	_____	_____	_____
g.	_____	_____	_____
h.	_____	_____	_____
i.	_____	_____	_____
j.	_____	_____	_____
k.	_____	_____	_____

40. How much time has the dietitian spent in patient care related activities preparing for and at this visit? (To be provided by the dietitian.)
(hh:mm)
41. How much time has the physician spent in patient care related activities preparing for and at this visit? (To be provided by the physician.)
(hh:mm)

Patient ID Number _____
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**Modification of Diet in Renal Disease Study
Demographic and Baseline Examination Form**

- 101. Date this form completed..... ___/___/___
- 102. Certification number of person filling out this form..... _____
- 103. Date form entered..... ___/___/___
- 104. Certification number of data entry person..... _____

**Modification of Diet in Renal Disease Study
MONTHLY EXAMINATION FORM**

This form is to be completed by the study coordinator, physician and dietitian at each monthly visit after Baseline 0. In addition, Refer to Page 10 for a schedule of forms completion. Even if the visit is missed, it is very important to complete, enter and transmit this form in a timely fashion.

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|--|
| 4. | a. Enter the actual date of the visit if the patient kept appointment. If the visit was missed, fill in the target date from the appointment schedule generated by the DCC and complete Form 05 as indicated. ONLY FOLLOW-UP VISITS CAN BE "MISSED".

b. Also, use visit type = K for all Study C post stop point visits. |
| 5. | a. A visit is considered missed if the patient is not able to be scheduled within the window specified in the Protocol. Missed visits in follow-up should not be made up. Move on to hold the next monthly visit in its window.

b. Keep the reasons to these general categories. |
| 6a. | This question was added 2/91 to address long term illness. |
| 7. | If the patient does not smoke, enter 00.00. |
| 9a. | Enter the patient's weight at the visit rounded to the nearest tenth of a kilogram. The Datalex range is 40-130. It should be measured and recorded twice. The dietitian does <u>not</u> need to be the person to complete this item. |
| 9b. | The patient's weight status should be recorded at each visit to assist in determining whether or not the patient has reached a weight action item. (Undesired weight loss of more than 5% of standard body weight from the B3 visit to a weight of 75-95% of standard body weight in a patient without edema, or loss of weight to less than 75% standard body weight.) Refer to Protocol. |
| 9c/d. | This question relates to the change in weight action items in January 1991. |
| 10. | Enter the code which best describes the amount of edema. |
| 11.-13. | At each patient visit, medications and dosages should be carefully reviewed. Changes should be recorded in the appropriate section. New drugs prescribed at a visit are recorded on that monthly visit form. 'Since the last monthly patient visit' means after the last visit, up to and including this visit. |

Modification of Diet in Renal Disease Study
MONTHLY EXAMINATION FORM

The code number from the attached list, the dosage, IN THE CORRECT UNITS, and the number of times/day should be listed for each drug the patient is taking presently.

Drug doses - If patient receives a dose which includes decimals (12.5 2 times a day) you must enter the decimal point in one of the dashes provided. Similar to completing Forms 24 and 25. If a dose is truly missing, enter 999999.

The following codes should be used as "times per day" if a drug is taken at unusual frequencies:

- 85 = once every 10 days
- 86 = once every other week
- 87 = four times per month
- 88 = once every 5 days
- 89 = two weeks/month
- 90 = 5 times per week
- 91 = every other day
- 92 = once a week
- 93 = 3/week
- 94 = 3 weeks/month
- 95 = once a month
- 96 = twice a week
- 97 = once every 3 weeks
- 98 = 4 times per week
- 99 = PRN

- 14. During baseline this should always be 2=No.
- 15. Any action items that the center is aware of at the time the form is completed should be recorded here. If yes, there will be at least one Form 23 completed. Central action item measurements will be reported to the Clinical Center when the data becomes available. Refer to the Protocol for a review of action items. Remember, there are no action items during Baseline.

2.76.1

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Modification of Diet in Renal Disease Study Monthly Examination Form

This form is to be completed by the study team at the time of each scheduled monthly clinic visit.

FORM # 05

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of this clinic visit (Enter target date from appointment schedule if missed)..... / /
- b. Visit Type (B = Baseline, F = Follow-up).....
- c. Visit Number.....

0.0 = Baseline Visit 0	1.0 = Follow-up Visit 1
1.0 = Baseline Visit 1	2.0 = Follow-up Visit 2
2.0 = Baseline Visit 2	3.0 = Follow-up Visit 3
3.0 = Baseline Visit 3	4.0 = Follow-up Visit 4 (etc.)

5. a. Was this visit missed? (outside window, not held) (1 = yes, 2 = no)

If yes,

- b. Reason visit was missed.....

1 = Short-term illness	8 = Forgot
2 = Long-term illness	9 = Patient refused
3 = Hospitalization due to short-term illness	10 = Weather
4 = Hospitalization due to long-term illness	11 = Moved
5 = Personal family business	12 = Could not contact
6 = Work related business	13 = Other (20 characters maximum)
7 = Vacation	(.....)
	14 = Unknown

If the visit was missed, skip to item 101.

If the visit was missed due to reason 3 or 4, complete the Unscheduled Attention Form (Form #10).

6. Has the patient had any illnesses or health concerns in the past month for which the patient was seen by a physician? (1 = yes, 2 = no) If hospitalized, Complete Unscheduled Attention Form (Form #10).....
- a. At the time of this visit does the patient have a long term illness? (1 = yes, 2 = no).....
7. How many packs per day does the patient smoke?.....

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Modification of Diet in Renal Disease Study Monthly Examination Form

13. Since the last monthly patient visit, did any drug doses change? (1 = yes, 2 = no).....

If yes,

	Code Number	Dosage	Times/Day
a.	_____	_____	_____
b.	_____	_____	_____
c.	_____	_____	_____
d.	_____	_____	_____
e.	_____	_____	_____
f.	_____	_____	_____

14. Did symptoms related to low blood pressure occur 2 or more days since the last visit?
(action item) (1 = yes, 2 = no).....

15. Were any action items identified locally since the last monthly visit? (1 = yes, 2 = no)

If yes, Complete Action Item Response Form (Form # 23)

16. How much time has the dietitian spent in patient care related activities preparing for and at
this visit? (To be provided by the dietitian.)
(hh:mm)

17. How much time has the physician spent in patient care related activities preparing for and
at this visit? (To be provided by the physician.)
(hh:mm)

101. Date this form completed..... / /

102. Certification number of person filling out this form

103. Date form entered..... / /

104. Certification number of data entry person

**Modification of Diet in Renal Disease Study
LOCAL LABORATORY MEASUREMENT FORM**

This form is to be completed whenever a local laboratory measurement is done for the study. It should be completed for scheduled routine study blood work and for action item repeated measurements. If and when extra blood work is done, not called for in the Protocol, do not complete the form.

QUESTION #

INSTRUCTIONS

4b. B is a baseline visit, F is a follow-up visit and A is an abbreviated follow-up visit after stop points. P is used for blood work immediately after stop and X is used for Study F patients and always use K for Study C post stop point visits.

c. Visit numbers are sequential as follows:

- | | |
|------------------------|--------------------------------|
| 0.0 = Baseline Visit 0 | |
| 1.0 = Baseline Visit 1 | 1.0 = Follow-up visit 1 |
| 2.0 = Baseline Visit 2 | 2.0 = Follow-up visit 2 |
| 3.0 = Baseline Visit 3 | 3.0 = Follow-up visit 3 |
| | 4.0 = Follow-up visit 4 (etc.) |

If blood work is done at BOA instead of B0 or to supplement B0 data, complete by indicating the visit number by 0.5.

5. At all visits requiring serum biochemistry lab work, this section must be completed. (See Table 9.1. of the Protocol) The following is a table of units and allowed Datalex ranges for each of the laboratory values to be recorded. Be sure to watch for action items. See Section 10.3.1, page 10.4 for a complete list of items and definitions of action items.

- | | | |
|------------------|--------|--------------|
| a. Creatinine | mg/dl | 0.1 - 15.0 |
| b. Urea Nitrogen | mg/dl | 10 - 180 |
| c. Sodium | mEq/L | 30 - 450 |
| d. Potassium | mEq/l | 3.0 - 7.0 |
| e. Chloride | mEq/l | 80.0 - 130.0 |
| f. Bicarbonate | mEq/l | 10 - 50 |
| g. Glucose | mg/dl | 1 - 900 |
| h. Calcium | mg/dl | 6.0 - 12.0 |
| i. Iron | mcg/dl | 10 - 220 |
| j. Magnesium | mg/dl | 1.0 - 5.0 |

- | | |
|----------------------|-------------|
| 6. a. WBC (x103/mm3) | 2.0 - 15.0 |
| b. Hemoglobin (g/dl) | 6.0 - 20.0 |
| c. Hematocrit (%) | 20.0 - 60.0 |

For each value entered in items 5 and 6 indicate whether it was a routine study protocol measurement for that visit or if it was measured as a response to an action item. If local lab work is done which is not required, do NOT complete form. If measure done as part of routine and for action, indicate measured in response to action item.

When a value is outside the above ranges, a -1 should be entered and a Form #24, Data-Out-Of-Range, completed.

Modification of Diet in Renal Disease Study
LOCAL LABORATORY MEASUREMENT FORM

6. (cont'd) The following is a conversion equation for those centers where it is necessary to convert data prior to form completion and entry.
Serum magnesium (mg/dl) = 1.2*Magnesium (mEq/L)
- 7b. The following medications should not be taken for 48 hours prior to blood measurements: NSAID, inhibitors of tubular creatinine secretion (cimetidine, trimethoprim) or agents which interfere with chemical determination of creatinine (cephalosporins).

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Form # 06
Page 1 of 2



Modification of Diet in Renal Disease Study Local Laboratory Measurement Form

This form is to be completed whenever a local laboratory measurement is done for the study.

FORM # 06

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of visit (or measurement)..... / /
- b. Visit Type.....
- c. Visit Number.....

For items 5 and 6 give reasons for lab work

- 1 = Routine study measurement
- 2 = Repeated measurement for action item

5. Serum Biochemistry	Value	Reason
a. Creatinine (mg/dl)	_____	_____
b. Urea Nitrogen (mg/dl)	_____	_____
c. Sodium (mEq/l)	_____	_____
d. Potassium (mEq/l)	_____	_____
e. Chloride (mEq/l)	_____	_____
f. Bicarbonate (mEq/l)	_____	_____
g. Glucose (mg/dl)	_____	_____
h. Calcium (mg/dl)	_____	_____
i. Iron (mcg/dl)	_____	_____
j. Magnesium (mg/dl)	_____	_____

**Modification of Diet in Renal Disease Study
Local Laboratory Measurement Form**

6. Hematology	Value	Reason
a. WBC ($\times 10^3/\text{mm}^3$)	_____	_____
b. Hemoglobin (gm/dl)	_____	_____
c. Hematocrit (%)	_____	_____

7. a. How many hours was patient fasting prior to blood being drawn?..... _____
b. Were medications (NSAIDS, cimetidine, trimethorprim, cephalosporins) appropriately withheld 48 hours prior to the blood test? (1 = yes, 2 = no)..... _____

101. Date this form completed..... ____/____/____
102. Certification number of person filling out this form _____
103. Date form entered..... ____/____/____
104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
RENAL DIAGNOSIS FORM

This form is to be completed at Baseline Visit 1 by reviewing historical information available from the patient and his medical records.

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|---|
| 4. | Enter a 1 if the patient's diagnosis a) has not been confirmed by renal biopsy, serological studies or radiographic procedures where indicated; b) the study physician has not seen the results of these studies directly; or, c) if the study physician has not seen the official reports documenting interpretation of these procedures.
Enter a 2 if the renal diagnosis has been established by renal biopsy, serological studies, or radiological procedures.
Enter a 3 if the diagnosis is not known. |
| 5. | Enter the numbers which best describe the patient's primary and secondary forms of renal disease. |
| 6. | Enter a 1 if the evidence described is available and supports the renal diagnosis. Enter a 2 if the information is not available. |

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Form # 07
Page 1 of 2



Modification of Diet in Renal Disease Study Renal Diagnosis Form

This form is to be completed at Baseline Visit 1 by reviewing the patient's medical history.

FORM # Q Z

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center
- 4. This patient's primary renal diagnosis is.....
 - 1 = Presumptive
 - 2 = Established
 - 3 = Unknown

If unknown, skip to Item 101.

- 5. a. Primary renal diagnosis.....
- b. Secondary renal diagnosis

<ul style="list-style-type: none"> 1 = Polycystic kidney disease 2 = Hereditary nephritis 3 = Analgesic nephropathy 4 = Pyelonephritis 5 = Other interstitial nephritis 6 = Obstructive uropathy - acquired 7 = Obstructive uropathy - congenital 8 = Vesico-ureteral reflux 9 = Urinary tract stones 10 = Hypertensive nephrosclerosis 11 = Diabetic nephropathy 12 = Renal artery stenosis 13 = Membranous nephropathy 14 = Focal sclerosis 	<ul style="list-style-type: none"> 15 = Membranoproliferative glomerulonephritis 16 = Mesangial proliferative glomerulonephritis 17 = Chronic renal failure with proteinuria 18 = Nephrotic syndrome without biopsy 19 = Absence of one kidney 20 = IgA nephropathy 21 = Other glomerulonephritis 22 = Other (20 characters maximum) (.....) 23 = Unknown 24 = None
---	---

- 6. Which of the following are available as supportive evidence for the patient's primary renal diagnosis? (1 = yes, 2 = no)
 - a. physical exam.....
 - b. history.....
 - c. family history.....
 - d. urinalysis.....
 - e. renal biopsy.....
 - f. abdominal plain film (KUB)
 - g. intravenous pyelogram.....

**Modification of Diet in Renal Disease Study
Renal Diagnosis Form**

6. (Continued)
- h. retrograde pyelogram.....
 - i. renal ultrasound.....
 - j. renal radionuclide scan (NMR).....
 - k. renal arteriogram.....
 - l. renal venogram.....
 - m. bladder ultrasound.....
 - n. CAT scan
 - o. voiding cytourethrogram
 - p. other (20 characters maximum)(.....)
101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Date form entered..... / /
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
SECONDARY SCREENING AFTER B3 OR BASELINE DROPOUT FORM

This form is to be completed once for each patient who enters baseline. It should be done as soon as the patient drops from baseline or after B3 prior to randomization.

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|--|
| 4. | Enter a 1 if patient is leaving the study prior to the Baseline 3 Visit and a 2 if the patient has had the Baseline 3 Visit. If 1, the patient is now part of Study F. Study F contact should be scheduled every four months from the date of the B0 visit. |
| 5. | Enter a 1 next to each condition contributing to patient dropout. Enter a 2 next to each condition that does not apply. |
| 7. | Enter a 1 if the patient's dietary preferences will interfere with study diet prescriptions. Enter a 2 if dietary preferences would allow compliance with study diet prescriptions. |
| 8. | Enter a 1 if the patient has become pregnant. Enter a 2 if the patient is not pregnant. |
| 9. | Enter a 1 if compliance is not expected; enter a 2 if compliance is likely. In items 9a.- l., enter a 1 next to all characteristics responsible for expected non-compliance; enter a 2 next to those categories that do not apply. |
| 10. | Enter a 1 if the patient has one or more of the renal disorders listed in items 10a.-e.; enter a 2 if none of these are present. In items 10a.-e., enter a 1 next to those renal disorders present; enter a 2 next to those not present. |
| 11. | Enter a 1 if urinary retention has been identified by history, physical examination or radiologic procedures. Enter a 2 if there is no urinary retention documented. |
| 12. | Enter a 1 if the patient has any of the disorders delineated in items 12a.- k.; enter a 2 if none of these disorders are present. For items 12a.- k., enter a 1 next to each medical condition characterizing the current state of the patient's health; enter a 2 next to those that do not apply. See instructions for Form #03 for specifics regarding each disorder. |

**Modification of Diet in Renal Disease Study
SECONDARY SCREENING AFTER B3 OR BASELINE DROPOUT FORM**

QUESTION # INSTRUCTIONS

13. Enter a 1 if the patient is currently taking any of the medications listed in items 13a.- h.; enter a 2 if the patient takes none of these.
b. The following doses of steroids are equivalent in glucocorticoid effect to the indicated dose of prednisone.

		<u>Equivalency</u>
Cortisol	30 mg	7.5 mg
Cortisone	37.5 mg	7.5 mg
Prednisolone	7.5 mg	7.5 mg
Dexamethadone	1.125 mg	7.5 mg
Triamcinolone	6 mg	7.5 mg
Methylprednisolone	6 mg	7.5 mg

14. Enter a 1 if the patient has a known allergy to iodine or iothalamate, or has had a previous adverse reaction to radiocontrast which would contraindicate the performance of an iothalamate (glofil) GFR procedure; enter a 2 if no such risk applies.
15. Enter a 1 if the patient does not wish to participate or is unable to give consent; enter a 2 if the patient is both willing and able to consent.
16. Enter a 1 if the patient is too uremic or has gone on dialysis. Enter a 4 if the reason the patient cannot enter the follow-up period has not been delineated by answering questions 1-16. Please specify the reason. Enter a 5 if the reason(s) have been delineated in items 1-16.
17. Enter a 1 if the patient is eligible to enter the study; enter a 2 if the patient is ineligible (items 4 or any of items 6-16 are 'yes'). If 2, the patient is now part of Study F and an annual visit should be scheduled.

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Form # 08
Page 1 of 4



Modification of Diet in Renal Disease Study Secondary Screening after B3 or Baseline Dropout Form

This form is to be completed at the end of the baseline period, prior to randomization, or as soon as the patient drops from the Baseline Period.

FORM # 08

1. Patient Identification Number.....
 2. Patient Name Code.....
 3. Clinical Center
 4. Is the patient leaving the study prior to Baseline Visit 3? (1 = yes, 2 = no).....
- If no, skip to Item 6.
If yes, the patient is now part of Study F. Continue with Item 5.
5. What are the reasons for the patient dropping? (1 = yes, 2 = no)
 - a. GFR judged to be too high
 - b. GFR judged to be too low
 - c. estimated protein intake less than 0.9 for Study A.....
 - d. adverse reaction to lothalamate.....
 - e. patient does not want to continue.....
 - f. dialysis.....
 - g. transplant.....
 - h. medical conditions.....
 - i. study team preference.....
 - j. compliance doubtful.....
 - k. Baseline visit 1 more than 3 months after B0.....
 - l. other (20 characters maximum)(.....)

Skip to Item 17.

Study Compliance

A report will be generated with the appropriate information. The DCC will store the following information from the report.

6. Has the patient failed to comply with study procedures?
 - a. Has the patient missed one or more baseline visits?
 - b. Has the patient failed to have a B0 or B3 GFR?
 - c. Have fewer than three 24-hour urine samples been successfully completed?

**Modification of Diet in Renal Disease Study
Secondary Screening after B3 or Baseline Dropout Form**

6. (Continued)
d. Has the patient completed fewer than 6 readable 1-day diet diaries between Baseline Visit 0 and Baseline Visit 3?

e. Was B1 more than 3 months after B0?

Note also, if otherwise eligible, the randomization must be done within 6 weeks of Baseline Visit 3.

7. Will diet preferences interfere with compliance to study diet? (example, some vegetarians) (1 = yes, 2 = no)

Exclusions

8. a. Has patient become pregnant? (1 = yes, 2 = no)
b. Is patient now likely to become pregnant? (1 = yes, 2 = no).....
9. Is compliance doubtful for one or more of the following reasons? (1 = yes, 2 = no)

If yes, (for items a through i, 1 = yes, 2 = no)

- a. drug abuse?.....
b. alcohol abuse?.....
c. major psychiatric illness (within past year)?.....
d. poor understanding of the study?.....
e. limited motivation?.....
f. transient residence?.....
g. unsuitable home environment?.....
h. cannot communicate well?.....
i. pattern of frequently missed clinic visits?.....
j. lack of access to a telephone?.....
k. poor compliance in other clinical trials?.....
l. other (20 characters maximum)(.....)
10. Does the patient have any of the following known renal disorders? (1 = yes, 2 = no).....
If yes, (for a through e, code 1 = yes, 2 = no)
a. urinary tract obstruction.....
b. renal artery stenosis as the cause of renal insufficiency.....
c. branched or staghorn calculi.....
d. kidney transplant recipient.....
e. cystinuria insufficiency

**Modification of Diet in Renal Disease Study
Secondary Screening after B3 or Baseline Dropout Form**

11. Does the patient have documented or known evidence of urinary retention? (1 = yes, 2 = no).....
12. Does the patient show evidence of any of the following known chronic serious medical conditions? (1 = yes, 2 = no)

If yes, (for items a through k, code 1 = yes, 2 = no)

- a. type I diabetes (fasting blood sugar >200 mg/dl) at the most recent visit.....
 - b. malignancy (within past year - exclude skin).....
 - c. heart disease NYHA class 3 or 4.....
 - d. severe chronic lung disease.....
 - e. liver disease
 - f. gastrointestinal disease (which affects diet)
 - g. chronic systemic infections (within past six months).....
 - h. collagen vascular disease (except for rheumatoid arthritis)
 - i. Has the patient been hospitalized more than three times in the past year?
 - j. Has the patient been in the hospital more than 60 days within the past year?.....
 - k. Is the patient disabled?.....
13. Is the patient taking any of the following medications? (1 = yes, 2 = no)

If yes, (for items a through h, 1 = yes, 2 = no)

- a. immunosuppressive agents
 - b. corticosteroids.....
 - c. gold (within past month).....
 - d. penicillamine (within past month).....
 - e. salicylates.....
 - f. other non-steroidal anti-inflammatory agents.....
 - g. investigational new drugs (excluding Erythropoietin).....
 - h. Erythropoietin
14. Does the patient have an allergy or adverse reaction to iodine or iothalamate? (1 = yes, 2 = no).....

Complete Blood Pressure Form.

15. Is the patient unwilling or unable to give consent? (1 = yes, 2 = no).....

**Modification of Diet in Renal Disease Study
Secondary Screening after B3 or Baseline Dropout Form**

16. Is there any other factor not previously noted on this form which will prevent the patient from entering follow-up?.....
- | | |
|---------------------------------------|-----------------------------------|
| 1 = Patient on dialysis or too uremic | 4 = Other (20 characters maximum) |
| 2 = Transplant | (_____) |
| 3 = Study team preference | 5 = No |

NOTE:

1. A final baseline 3 report will be sent by the DCC with final status of GFR, Body Weight, Blood Pressure, Creatinine, Urinary Protein Excretion, Estimated Protein Intake and Albumin. The blood pressure and/or albumin may have been repeated once if the Baseline 3 result was out of range. Both the results of that report and the results of this form must state that the patient is eligible (Items 5-16 are no) in order to call for a random diet and blood pressure group assignment.

2. If the patient is ineligible, the patient is now part of Study F.

17. Is the patient eligible to enter the study? (1 = yes, 2 = no).....

If the patient is eligible, and has given his/her consent, then call to randomize the patient.

101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Physician's signature
104. Certification number of physician
105. Has form been signed by physician? (1 = yes, 2 = no)
106. Date form entered..... / /
107. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
RANDOMIZATION FORM

The Study Coordinator should complete this form during the randomization phone call to the DCC.

<u>QUESTION #</u>	<u>INSTRUCTIONS</u>
4-5.	It is very important that a copy of the signed consent form be completed (and sent to the DCC) prior to randomization.
6.	Enter the date the DCC is called and a random diet and blood pressure group assignment is given.
7.	Enter a 1 if Diet K (0.28 g/kg/day + ketoacid supplementation) is the randomized diet. Enter a 2 if Diet L (0.55-0.60 g/kg/day) is the randomized diet. Enter a 3 if Diet M (1.0-1.4 g/kg/day) is the randomized diet.
8.	Enter the Blood Pressure Group the patient is assigned to.

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Form # 09
Page 1 of 1



**Modification of Diet in Renal Disease Study
Randomization Form (Clinical Center)**

This form is to be completed by the study coordinator during the phone call when a patient is randomized.

FORM # 09

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. Has a copy of the appropriate Informed Consent Form been signed by the patient?
(1 = yes, 2 = no)
5. Date form sent to the Data Coordinating Center / /
6. Date of Randomization..... / /
7. Diet assigned
 1 = Diet K
 2 = Diet L
 3 = Diet M
8. Blood Pressure Group assignment
 1 = Moderate MAP Goal
 2 = Low MAP Goal
101. Certification number of person filling out this form
102. Date form entered..... / /
103. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
UNSCHEDULED MEDICAL ATTENTION FORM

This form is to be completed when a patient is hospitalized for any reason.

QUESTION #INSTRUCTIONS

4. b. Sequence Number:
 1 = First of one or more visits to a physician or physicians occurring on this date by this patient.
 2 = Second of two or more visits to a different physician or physicians occurring on this same date as previously noted on the first Unscheduled Medical Attention Form by this patient.
 3 = Third of three or more visits etc....
5. Keep this to these general categories. Phone consultation may be considered "other". As of 3/1/90, the answer to this should always be 5=hospitalization. No need to complete this form otherwise.
- 5a-d. Identify dates and codes as they relate to hospital admission. The diagnoses and surgery codes are important. Do the very best you can to get the appropriate codes.
6. Reason for Medical Attention:
 1 = No problem, i.e., routine check-up to non-study physician.
 2 = Mild, i.e., renewing drugs, blood pressure check, of non-emergency condition
 3 = Moderate, i.e., required time off from work, interfered with normal daily activities and required attention.
 4 = Severe, i.e., required hospitalization, cast-broken bones.
 5 = Surgery required.
 9 = not applicable
- 7b. Indicate the total number of days the patient has been off the study diet. If the patient eventually reaches a stop, indicate the number of days up until the date of the stop point.
8. The physician's name, and business address should be clearly PRINTED and entered into Datalex. HCFA will use this information when necessary to access financial information. PRINT LEGIBLY. The title should be abbreviations as follows:
 MD, PHD, DDS, RN, DO. Do not use Dr. as part of physician's first name.
- VA can be abbreviated. Left justify. Complete as much of the name as possible.

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Rev. 2 12/1/90

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MDRD

Modification of Diet in Renal Disease Study Unscheduled Medical Attention Form

This form is to be completed when a patient is hospitalized.

FORM # 10

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of Medical Attention / /
- b. Sequence Number (1st, 2nd, 3rd visit in same day).....
5. Type of Attention.....

1 = Clinic visit	5 = Hospitalization
2 = Visit to non-study physician	6 = Other
3 = Emergency room	(.....)
4 = House call	9 = Unknown

If hospitalization,

- a. Date of admission / /
- b. Date of discharge..... / /
- c. Primary diagnosis (ICD-9).....
- d. Surgery code (ICD-9).....

6. Reason for Medical Attention

For the following enter:

- | | |
|----------------|----------------------|
| 1 = No problem | 4 = Severe |
| 2 = Mild | 5 = Surgery required |
| 3 = Moderate | 9 = Not applicable |

Related to:

- a. kidney disease
- b. brain/nervous system.....
- c. eyes/vision.....
- d. ears/hearing.....
- e. heart.....
- f. vasculature.....

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**Modification of Diet in Renal Disease Study
Unscheduled Medical Attention Form**

6. (Continued)
- g. lungs.....
 - h. liver.....
 - i. spleen/lymph.....
 - j. muscles.....
 - k. bones.....
 - l. joints.....
 - m. skin.....
 - n. gastrointestinal.....
 - o. gynecology.....
 - p. dentist.....
 - q. placement of vascular access.....
 - r. other(_____).....
7. a. Did patient go off study diet due to illness? (1 = yes, 2 = no).....
- b. Number of days patient was off diet.....
8. a. Physician providing unscheduled care (must be entered)
- First Name... _____
- Last Name... _____
- Title..... _____
- b. Location of physician:
- Hospital _____
- Address _____
- City..... _____
- State..... _____
- Zip Code..... _____

Patient ID Number _____
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Form # 10
Page 3 of 3

**Modification of Diet In Renal Disease Study
Unscheduled Medical Attention Form**

- 101. Date this form completed..... ____/____/____
- 102. Certification number of person filling out this form _____
- 103. Physician's signature _____
- 104. Certification number of physician _____
- 105. Has form been signed by physician? (1 = yes, 2 = no) _____
- 106. Date form entered..... ____/____/____
- 107. Certification number of data entry person _____

**Modification of Diet in Renal Disease Study
STOP POINT FORM**

This form must be completed by the study coordinator and/or physician when a stop point has been reached. Refer to section 13 of the Protocol for a detailed review of each stop point. The Review Committee should be contacted to confirm that a stop point has been reached prior to completing this form.

QUESTION # INSTRUCTIONS

4. Enter the code associated with the Study which the patient has been part of until the time the stop point occurred.
5. Enter the code associated with the Diet which the patient has been on.
6. Enter the date that the stop point was declared.

Item 6 on the Stop Point Form is the date the stop point is declared. Generally speaking, this will be the day that the team at your clinic decides that, yes, this person needs to be on dialysis as soon as possible. So, you file the Form 11, enter the "date the stop point is declared", and, if the patient actually starts dialysis before you file the form, you can enter "date dialysis began" for item 12b. (If you do not yet know the date the dialysis began, you can get this to us later in 11b. on a future Form 12 for an abbreviated, post stop point visit.)

The reason for this reminder is the P1 visit. Recall that the Protocol requires a special post stop point (P1) visit within two weeks of the stop point being declared. This should, of course, be held as soon as possible after the stop point. But, if you were to use the date of dialysis as the date the stop point is declared, and if that date is several weeks in the past, you would already be outside the window of the P1 visit. Those P1 data are important. Using the date your team was aware of the stop point will guarantee you have time for the post stop point visit.

7. If the patient is not in Study A, item 7 is blank. It will be skipped on the data entry screen.
 - a. Enter yes if the GFR is <50% of the Baseline 3 GFR or if the GFR has fallen to ≤ 20 ml/min/1.72m². The DCC will provide this information in a report if it occurs.
 - b. If the patient was part of Study A and reached ONLY a renal function stop point, the patient is now eligible for Study C. Review informed consent and complete Form #31 if patient will continue in Study C.

Items 8-13 should reflect the primary reason a stop point is being declared. Only one of these items should reflect a positive response.

**Modification of Diet in Renal Disease Study
STOP POINT FORM**

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|--|
| 8. | Enter a 1 if serum albumin has been <3.0 g/dl on two successive monthly determinations after the energy and protein prescriptions have been altered to improve serum albumin. (Note that low serum albumin due to intercurrent illness does not comprise a stop point.) Enter a 2 if serum albumin is >3.0 g/dl. |
| 9. | Enter a 1 if there has been weight loss resulting in a body weight <75% of the patient's standard body weight (SBW) despite an increase in the patient's energy intake. Enter a 2 if body weight is >75% SBW. |
| 10. | Enter a 1 if serum phosphorus \geq 6.0 mg/dl for four consecutive months despite: 1) review of dietary phosphorus and further restriction where possible; 2) addition of aluminum phosphate binders; and 3) measurement of serum inorganic phosphate with the patient fasting overnight. Enter a 2 if serum phosphorus is <6.0 mg/dl. |
| 11. | Enter a 1 if the patient has developed acute renal failure.
Enter a 2 if a serious medical condition has occurred (outlined in detail previously in the instructions for the Screening Form). Enter the name of this medical condition (in the space provided).
Enter a 3 if there is no serious medical condition that would be considered the primary reason for a stop point. |
| | If a patient is going on dialysis, item 11 should be 3, no, and item 12 completed. |
| 12. | Enter a 1 if patient will go on dialysis. Enter the date of the first dialysis if it has already occurred. Enter the type of dialysis. Enter a 2 if dialysis is not applicable. |
| 13. | Enter a 1 if the patient will have transplant. Enter the date of transplantation if it has already occurred. Enter a 2 if the patient will not be transplanted. |
| 14. | Enter yes or no for each of the diets prescribed for the patient now that a stop point has been reached. |
| 15. | Enter a 1 if the patient's medical regimen will change with regard to anything other than diet, medications, dialysis or transplantation as described above. Please specify. |

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MDRD

Modification of Diet in Renal Disease Study Stop Point Form

This form is to be completed when a stop point has been reached. The Clinical Management Committee should be contacted prior to completing this form.

FORM # 1 1

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. Study (1 = A, 2 = B, 3 = C).....
5. Diet.....
 - 1 = Diet K
 - 2 = Diet L
 - 3 = Diet M
6. Date stop point is declared...../...../.....

Note: Only one of items 7 to 13 can and should be answered yes in order for the patient to be at a stop point. The patient should not reach more than one stop.

7. a. Has the patient reached a GFR stop point? (Study A patients only.) (1 = yes, 2 = no) ..

The DCC will send a report.

A patient is eligible for Study C if the patient was in Study A and reached only a renal function stop point.

- b. Is this patient eligible for Study C? (1 = yes, 2 = no) ..

If yes, initiate Study C informed consent procedures. Complete Study C Assignment Form #31.

For All Study Patients

8. Is serum albumin still less than 3.0 g/dl after dietary intervention for the Low Serum Albumin Action Item? (Protocol, Section 13) (1 = yes, 2 = no) ..
9. Has body weight decreased to below 75% of standard body weight for 3 months after dietary intervention for the Weight Loss Action Item? (Protocol, Section 13) (1 = yes, 2 = no) ..
10. Has serum phosphorus been greater than or equal to 6.0 mg/dl on four consecutive monthly measurements after intervention for very high Serum Phosphorus Action Item? (Protocol, Section 13) (1 = yes, 2 = no) ..

Patient ID Number _____
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Form # 11
Page 3 of 3

**Modification of Diet in Renal Disease Study
Stop Point Form**

- 101. Date this form completed..... ____/____/____
- 102. Certification number of person filling out this form _____
- 103. Physician's signature _____
- 104. Certification number of physician _____
- 105. Has form been signed by physician? (1 = yes, 2 = no) _____
- 106. Date form entered..... ____/____/____
- 107. Certification number of data entry person _____

Modification of Diet in Renal Disease Study
ABBREVIATED FOLLOW-UP FORM

This form is to be used every four months for patients reaching a stop point who do not enter Study C.

The Study Coordinator should be responsible for completing the form. Be sure to complete the necessary forms for blood work, dietary review and GFR as explained in the instructions.

QUESTION # INSTRUCTIONS

4. c. Visit Number. The patient's abbreviated visit should be numbered as if you would have been seeing the patient monthly. For example, stop point visits will be numbered A 4.0, A 8.0, A 12.0 or A 16.0 etc. The abbreviated visits after a stop point should fall at the regularly scheduled follow up visit 4, 8, 12 etc... If a stop point is reached at F3, the first abbreviated visit would be one month later and be labeled A4. The next would be 4 months after that and labelled A8. If a stop point is reached at F5 then the first abbreviated visit would be 3 months later and labelled A8. The appointment schedule should thus remain helpful. However, rather than a 15 day window you can expand to \pm 30 days from the target. Thus, refer to target date, not first and last possible dates.
5. If the visit is missed, skip to Item 11. You may still obtain information for 11-13. If the patient could not be contacted or the data for 11-13 is not known, enter a blank.
6. The patient's actual body weight should be recorded in kilograms to the nearest tenth. It should be measured and recorded twice by any team member. The dietitian is responsible for completing an Anthropometry Form. The Datalex range is 40 to 130 kg.
7. Enter the code which best describes the degree of edema.
8. Referring to the drug list, complete the first space with the drug code if the patient is taking the medication presently.

Complete the second and third parts to the item as thoroughly as possible. Mark the amount of the drug being taken in the units which have been specified and the number of times per day. PRN drugs should be given a code of 'Times/Day' of 99. See instructions for Form 5, page 2.76.1, for description of frequency codes.

Medications altered at this visit should be recorded here now, not at the next visit.
9. If the patient has had any illnesses since the last visit for which they were hospitalized, enter a 1. If not, enter a 2.
10. If the patient does not smoke, enter 00.00.

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Modification of Diet in Renal Disease Study
ABBREVIATED FOLLOW-UP FORM

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|---|
| 11. | a. If the patient has begun dialysis, enter a 1. If not, enter a 2.
b. Enter the date the patient began on dialysis.
c. Enter the code describing the type of dialysis the patient is on. |
| 12. | a. If the patient has had a transplant, enter a 1. If not, enter a 2.
b. Enter the date of the transplant. |
| 13. | Enter diets patient is currently following. |
| 14., 15. | If the visit was missed, still complete with any amount of time spent in between visits. If no time was spent, enter 0. |

**Modification of Diet in Renal Disease Study
Abbreviated Follow-Up Form**

Drugs/Nutritional Supplements

8. Referring to the Drug list in the Manual of Operations, list all drugs the patient is currently taking. Pay careful attention to units.

	Code Number	Dosage	Times/Day
a.	_____	_____	_____
b.	_____	_____	_____
c.	_____	_____	_____
d.	_____	_____	_____
e.	_____	_____	_____
f.	_____	_____	_____
g.	_____	_____	_____
h.	_____	_____	_____
i.	_____	_____	_____
j.	_____	_____	_____
k.	_____	_____	_____
l.	_____	_____	_____
m.	_____	_____	_____
n.	_____	_____	_____
o.	_____	_____	_____

9. Has the patient had any new illnesses for which he/she was hospitalized since the last visit? (1 = yes, 2 = no)

If yes, complete the **Unscheduled Attention Form (Form #10)**

10. How many packs per day does the patient smoke?.....

11. a. Has the patient begun dialysis? (1 = yes, 2 = no)

b. Date dialysis began..... / /

c. Type of dialysis.....

- 1 = Hemodialysis
- 2 = Home hemo
- 3 = CAPD
- 4 = CCPD
- 5 = IPD
- 9 = Unknown

12. a. Has patient had a transplant? (1 = yes, 2 = no).....

b. Date of transplant..... / /

**Modification of Diet in Renal Disease Study
Abbreviated Follow-Up Form**

13. Is the patient currently following any special diet therapy? (1 = yes, 2 = no)
- a. Very low protein (with supplements)....._____
 - b. Low protein....._____
 - c. Low salt....._____
 - d. Low calorie....._____
 - e. Other (20 characters maximum)(_____)....._____
14. How much time has the dietitian spent in patient care related activities preparing for and at this visit? (To be provided by the dietitian.)
(hh:mm) _____:_____
15. How much time has the physician spent in patient care related activities preparing for and at this visit? (To be provided by the physician.)
(hh:mm) _____:_____
101. Date this form completed..... ____/____/____
102. Certification number of person filling out this form _____
103. Date form entered..... ____/____/____
104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
ANNUAL FOLLOW-UP INFORMATION FORM

This form is to be completed by the Study Coordinator at each annual follow-up visit (F-12, etc.) in addition to the monthly visit form. Directions for all questions can be found in the Form #04 instructions. For Study F and stop point patients complete annually - every 3rd visit and do not complete items 17 or 18 for these patients.

If the times or costs in item 16a-f are zero, enter zeros. If the times or costs are unknown, enter all 9's.

QUESTION #INSTRUCTIONS

9-10.

The following is the list of income categories:

1 = < \$7,500	4 = 25,000 - 39,999
2 = 7,500 - 14,999	5 = 40,000 - 49,999
3 = 15,000 - 24,999	6 = 50,000 - 74,999
	7 = ≥ 75,000
	9 = unknown

15.

Height should be measured by the dietitian twice and recorded here. Standard body weight will not be recalculated.

17-18.

For Study F and Stop Point patients these questions may be skipped.

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Rev. 2 10/15/88

E ___
V ___
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Form # 13
Page 1 of 3



Modification of Diet in Renal Disease Study Annual Follow-up Information Form

This form is to be completed at Follow-Up Visits 12, 24, 36 and 48 for all study participants in Studies A, B, and C in addition to routine forms for the visit. Also complete the form annually for Study F and Stop point patients.

FORM # 13

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of visit..... / /
- b. Visit Type.....
- c. Visit Number.....
5. Education.....

1 = College graduate with professional training	5 = Completed 10-11 years of school
2 = College graduate	6 = Completed 7-9 years of school
3 = At least one year of college	7 = Completed <7 years of school
4 = High school graduate	9 = Unknown
6. Occupation. (Enter a number, 1-9, from list for Form 4. If not presently employed, please indicate most recent occupation.).....
7. Is the patient a full-time homemaker? (1 = yes, 2 = no).....
8. a. Current Employment Status.....

1 = Full time	6 = Retired due to disability
2 = Part time	7 = Other (20 characters maximum)
3 = Unemployed not due to disability	(.....)
4 = Unemployed due to disability	9 = Unknown
5 = Retired not due to disability	
- b. If unemployed due to disability, is it a renal disability? (1 = yes, 2 = no).....
- c. If working part time only, is this due to a renal disability? (1 = yes, 2 = no).....
- d. If working full or part time, how many days in the past year did the patient miss work due to illness?.....
- e. If working full or part time, what is the patient's current wage rate?..... \$.....
- f. Is this rate hourly, weekly, or monthly? (H = hourly, W = weekly, M = monthly).....
9. What is the patient's gross annual income presently? (Enter the code for the appropriate income category from the instructions).....
10. a. What is the total household gross yearly income? (Enter the code for the appropriate income category from the instructions).....
- b. How many people are supported, in part or whole, from the total household income?.....

**Modification of Diet in Renal Disease Study
Annual Follow-up Information Form**

11. Does the patient currently smoke cigars or pipes? (1 = yes, 2 = no).....
12. a. Religion.....
1 = Catholic
2 = Protestant
3 = Jewish
4 = Other (20 characters maximum)
(_____)
5 = None
6 = Unknown
- b. Does the patient feel that his or her religious practices influence his or her diet?
(1 = yes, 2 = no).....
If yes, specify _____
13. Marital Status.....
1 = Single
2 = Married
3 = Separated
4 = Divorced
5 = Widowed
9 = Unknown
14. Living Arrangements (1 = yes, 2 = no)
a. alone.....
b. with spouse.....
c. with children.....
d. with parents.....
e. with other relatives.....
f. with friends.....
(To be provided by the dietitian)
15. Height (cm) 1.).....
2.).....
16. a. Estimated average round trip travel time to clinic for each visit (hh:mm).. :
b. Estimated average lost work time for each visit (hh:mm) :
c. Estimated average round trip travel cost for each visit to clinic..... \$
d. Average amount of lost wages per clinic visit..... \$
e. Average amount of child care costs per clinic visit..... \$
f. Average other costs per clinic visit..... \$
17. a. Suppose it is found conclusively that this diet will delay the onset of kidney failure requiring kidney dialysis or transplantation. If the government were to pay for the costs of this treatment, much like the case in this trial, does the patient say he or she would recommend dietary treatment to a close friend in a similar situation?
(1 = yes, 2 = no).....
If yes,
b. How strongly would the therapy be recommended?.....
1 = Very strongly without reservation
2 = Very strongly with reservation
3 = Moderately without reservation
4 = Moderately with reservation

**Modification of Diet in Renal Disease Study
Annual Follow-up Information Form**

17. (Continued)
- c. Suppose the cost of the treatment were \$50.00 per month, not covered by insurance. Would the patient still recommend diet therapy to his or her friend? (1 = yes, 2 = no).....
 - d. Suppose the cost were \$100.00 per month. Would the patient still recommend diet therapy to his or her friend? (1 = yes, 2 = no).....
18. Suppose it is found conclusively that this diet will delay the onset of kidney failure requiring dialysis or transplantation, and the diet, physician services, medical care, counselling and food/drug supplements may cost up to \$300 per month. How much would the patient be willing to pay out of pocket (not covered by insurance) each month to continue the diet?
(Start with the highest amount and ask for a yes/no response. Continue until the first yes answer is given.)(1= yes, 2=no)
- a. \$300 per month.....
 - b. \$250 per month.....
 - c. \$200 per month.....
 - d. \$150 per month.....
 - e. \$100 per month.....
 - f. \$50 per month.....
 - g. \$25 per month.....
 - h. \$10 per month.....
 - i. Unknown.....
101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Date form entered..... / /
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

**Modification of Diet in Renal Disease Study
REASON FOR MULTIPLE MISSED FOLLOW-UP VISITS FORM**

This form is to be completed if despite all efforts, a patient has missed four or more consecutive follow-up visits. Generally, this only needs to be completed once.

There are two instances when Form 14 should be completed more than one time for a patient.

- a.) If new information becomes available. This may happen through continued efforts to have the patient attend a visit.

- b.) If the string of 4 or more missed visits is broken (by the patient attending one or more visits) and then another 4 or more consecutive visits are missed.

For each reason, items 6-15 enter a 1 if the statement is true or a 2 if it does not apply to this patient.

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**Modification of Diet in Renal Disease Study
Reason for Multiple Missed Follow-Up Visits Form**

Once a patient has been randomized, he or she becomes part of the follow-up group for the MDRD Study and should adhere to his or her follow-up visits and procedures, whether or not he or she is complying to a diet. If, despite the best efforts of the MDRD team, a patient misses four or more consecutive follow-up visits, this form should be filed to explain what has happened. The patient should still be encouraged to come to his or her annual visits.

FORM # 14

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center
- 4. a. Date of Last Follow-Up Visit Held..... / /
- b. Visit Type.....
- c. Visit Number.....

Reasons for Missed Follow-Up Visits
(For the following, enter 1 = yes, 2 = no)

- 5. Are the reasons for the patient missing his or her follow-up visits known? (1 = yes, 2 = no).....
If no, skip to Item 101.
- 6. The patient has moved to a location which is not near an MDRD Clinical Center (Remember to get new address).....
- 7. The patient's physician has asked him or her to withdraw from the study
- 8. The patient is unwilling to have additional GFR measurements.....
- 9. The patient is unhappy with the frequency of the follow-up visits.....
- 10. The patient is discouraged in trying to comply to his or her randomized diet assignment
- 11. The patient thinks his or her randomized diet assignment is not good for his or her health.....
- 12. The patient has a new job or a new situation at work which makes participation burdensome
- 13. The patient is discouraged in trying to comply to his or her blood pressure control regimen
- 14. The patient is having problems with the combination of diet and blood pressure control
- 15. Other (.....)

**Modification of Diet in Renal Disease Study
Reason For Multiple Missed Follow-Up Visits Form**

16. Please explain the reasons further in the spaces below. 50 characters will be entered into the database.

101. Date this form completed..... _ _ / _ _ / _ _

102. Certification number of person filling out this form

103. Date form entered..... _ _ / _ _ / _ _

104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
DEATH NOTIFICATION FORM

This form should be completed for all patients who have died, after the details and cause of death are known. It should be completed by the Study Coordinator or Study Physician.

<u>QUESTION #</u>	<u>INSTRUCTIONS</u>
5.	Enter the code best describing the primary reason for the patient's death. If it is something other than what is listed, enter a 10 and specify the reason in the space provided. If the cause is unknown, enter a 9.
6.	If an autopsy has been done, enter a 1. If not, enter a 2. THE DATA COORDINATING CENTER REQUESTS THAT A COPY OF THE AUTOPSY REPORT AND THE DEATH CERTIFICATE BE FORWARDED TO THE DCC PROMPTLY.
7.	Enter the code which best describes the location of the patient at the time of death. If unknown, enter a 9.
8.	Any comments which should be recorded may be written in the space provided.

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Rev. 1 9/1/88

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Form # 15
Page 1 of 2

MDRD

Modification of Diet in Renal Disease Study Death Notification Form

This form is to be completed for any study participant upon learning the patient's cause of death.

FORM # 1 5

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. Date of Death..... / /
5. Cause of Death.....

1 = Cardiovascular Disease	7 = Respiratory Disease
2 = Septicemia	8 = Cerebrovascular Accident
3 = Cancer	9 = Unknown
4 = Trauma	10 = Other (20 characters maximum)
5 = Suicide	(_____)
6 = Renal Disease	

6. Has an Autopsy been done? (1 = yes, 2 = no).....

The Data Coordinating Center will request that a copy of the death certificate and autopsy report be submitted as soon as they become available.

7. Location of Death.....

1 = During hospitalization	5 = Other (20 characters maximum)
2 = At home	(_____)
3 = At work	9 = Unknown
4 = En route to hospital	

8. Comments:

Patient ID Number _____
Rev. 1 9/1/88

Form # 15
Page 2 of 2

**Modification of Diet in Renal Disease Study
Death Notification Form**

101. Date this form completed..... _ _ / _ _ / _ _
102. Certification number of person filling out this form _ _ _ _ _
103. Date form entered..... _ _ / _ _ / _ _
104. Certification number of data entry person _ _ _ _ _

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
GFR DETERMINATION WORKSHEET FORM

This form should be completed by the GFR nurse/technician or other GFR certified personnel. Be sure that times are recorded in 24-hour clock. Include a copy of this form with the samples being shipped to the Central GFR Lab. Complete, enter and transmit the form in the usual manner. Complete this form for all required GFR's, whether they were done or not.

QUESTION # INSTRUCTIONS

- 4 b.c. Visit type and number for routine GFR's inside their windows must be the scheduled protocol visit numbers regardless of which visit the GFR procedure was actually done. (i.e., B0, B3, F2, F4, F8, F12, etc...) The GFR must be done in its \pm 30 day time schedule from the target date. If not, it is an unrequired GFR and 4d would be labelled as 4 = not required by protocol. Only 1 GFR form should be transmitted for each protocol GFR.

If the B-3.0 GFR CV is not within range, but otherwise valid, the GFR can be "repeated" by holding another GFR visit within the allowable Baseline period and labelling it as visit number 3.9.

- 4 d. For choices 3 and 4 in item 4d enter the visit type and number of the most recent scheduled monthly visit prior to this GFR test (i.e. If item 4d = 3 then use the most recent visit held).

For choice 2, visit type = P and visit number = 1.0 (unless it is a Study C patient who has reached a second stop point (VISN = 2.0).

P = Soon after stop point.

This should be used to identify the GFR done after a stop point is reached. Following this, visits at 4 month intervals will be labelled A.

If the GFR was repeated for an action item, but was not repeated until the next regularly scheduled GFR (4 months later), Q04D should reflect a code of 1.

- 5-6. Pregnancy testing is required on all menstruating (able to become pregnant) females. If the pregnancy test was not completed, the GFR must be rescheduled. If it is found to be positive, notify the physician. DO NOT DO GFR.

- 10 b. Check to see if the patient has had any non-steroidal anti-inflammatory agents (including aspirin), cimetidine, ranitidine, trimethoprim/sulfamethoxazole or trimethoprim. Be careful, this question is worded backwards from the way it is asked on Form 17.

11. Answer yes only if an "acceptable" GFR test was performed that will result in a GFR being calculated. Two period GFR's are not considered acceptable except for the B-0.0 GFR.

Modification of Diet in Renal Disease Study
GFR DETERMINATION WORKSHEET FORM

QUESTION # INSTRUCTIONS

16. Complete urine flow rate worksheet to determine if patient is hydrated enough to continue test.
- 17.- 21. Time interval between Time #0, #1, #2, #3, and #4 must be a minimum of 30 minutes. See the manual of operations for a complete discussion of GFR Methods. ALL TIMES SHOULD BE RECORDED AS 24-HOUR CLOCK TIMES.
22. As specified in the Manual of Operations, if during any period either 1) the urine collection is incomplete or 2) the urine collection is contaminated with feces, the results of that period cannot be calculated. In this case, a fifth period should be collected.

For split sample QC, after you have received the original GFR report and know it was analyzable, then you can submit Form 22 and the QC Form 16. The QC Id and namecode, a "fake" date of GFR (3-14 days after the original) and the rest of the form should be copied from the original except for questions 101-103.

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Form # 16
Page 1 of 4

MDRD

Modification of Diet in Renal Disease Study GFR Determination Worksheet Form

This form is to be completed for ALL required GFR tests.

FORM # 16

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of GFR test / /
- b. Visit Type
- c. Visit Number.....
- d. Type of GFR.....
 - 1 = Regularly scheduled GFR
 - 2 = 2 weeks after stop point
 - 3 = Repeat within one month of GFR action item
 - 4 = Not required by Protocol

Pregnancy Testing

5. Is the patient able to become pregnant? (1 = yes, 2 = no).....
If no, skip to Item 7.
 6. a. Was the pregnancy test performed? (1 = yes, 2 = no).....
If no, skip to Item 7.
 - b. Has a copy of the written report of results been obtained? (1 = yes, 2 = no)
 - c. Date of pregnancy test..... / /
 - d. Result (1 = positive, 2 = negative)
- If positive, do not perform the GFR. Notify the physician.
7. Did the patient have a short-term illness as defined in the protocol on the day of the GFR?
(1 = yes, 2 = no).....
 8. Have any new serious medical conditions developed (as defined in the protocol)? (1 = yes, 2 = no).....

If yes, notify the Principal Investigator, who will determine if the study should be performed or rescheduled. Complete the Unscheduled Attention Form if appropriate.

**Modification of Diet in Renal Disease Study
GFR Determination Worksheet Form**

9. Has the patient been fasting for at least 8 hours? (1 = yes, 2 = no).....
10. a. Has the patient had any radionuclide diagnostic tests OTHER than ones done with 99-Technetium (⁹⁹Tc as in ⁹⁹Tc-DTPA, renal flow scan) within the past 30 days? (1 = yes, 2 = no).....

If yes, DO NOT DO GFR. Reschedule test for a date at least 30 days from date of radionuclide test.

- b. Has the patient taken any NSAIDS (Motrin, Advil, etc..See MOP) in the past 48 hours? (1 = yes, 2 = no).....

If yes, DO NOT DO GFR. Discontinue medications and reschedule GFR 48 hours after last medications taken.

NOTE: Usual diuretics and antihypertensive agents should not be withheld prior to the GFR test.

If the answer to item 7 is "yes" or 9 is "no" or 10 a or b is "yes", the study should not be performed on this date. Try to reschedule within window.

11. Was GFR test performed? (1 = yes, 2 = no).....

If GFR was not done, skip to item 25.

12. Is ¹²⁵I-sodium iothalamate (Glofil) being used? (1 = yes, 2 = no).....

13. a. Did the patient take 5 ml/kg water load at home? (1 = yes, 2 = no).....

- b. Did the patient receive 10 ml/kg water load during first 60 to 90 minutes at the clinic? (1 = yes, 2 = no).....

- c. Did the patient receive an additional 200-400 ml of water every hour after the first hour during the visit? (1 = yes, 2 = no).....

- d. If the patient did not receive 200-400 ml water load every hour how much was received? (ml/hour).....

Record Times in military time, i.e. record 1:00 p.m. as 13:00.

14. a. Has SSKI been given? (1 = yes, 2 = no).....

- b. If yes, time (24-hour clock)..... : ..

15. a. Has Background Blood been drawn? (1 = yes, 2 = no).....

Have patient void. Collect urine, labelling it Background Urine.

- b. Time Background Urine collected (24-hour clock)..... : ..

- c. Volume of Background Urine (cc).....

16. Inject Glofil subcutaneously.
Time of injection (hrs:min)..... : ..

Modification of Diet in Renal Disease Study GFR Determination Worksheet Form

Wait at least 60 minutes but not more than 90 minutes to collect discard urine. Complete urine flow rate worksheet (FORM #16w) to determine if patient is hydrated enough to continue. Complete Item 17 with totals from worksheet.

17. a. Time #0 (hours:minutes)..... : _____
Have patient void. Collect urine, labelling it **Discard Urine**.
- b. Volume of **Discard Urine** (cc)..... _____
c. Urine Flow Rate at Time #0 (ml/min)..... _____
d. Has **Blood #0** been drawn? (1 = yes, 2 = no)..... _____
18. a. Time #1 (hours:minutes)..... : _____
b. Volume of **Urine #1** (cc)..... _____
c. Has **Blood #1** been drawn? (1 = yes, 2 = no)..... _____
19. a. Time #2 (hours:minutes)..... : _____
b. Volume of **Urine #2** (cc)..... _____
c. Has **Blood #2** been drawn? (1 = yes, 2 = no)..... _____
20. a. Time #3 (hours:minutes)..... : _____
b. Volume of **Urine #3** (cc)..... _____
c. Has **Blood #3** been drawn? (1 = yes, 2 = no)..... _____
21. a. Time #4 (hours:minutes)..... : _____
b. Volume of **Urine #4** (cc)..... _____
c. Has **Blood #4** been drawn? (1 = yes, 2 = no)..... _____
22. Optional 5th Period (To be done when a problem occurs during one of the first four periods)
- a. Time #5 (hours:minutes)..... : _____
b. Volume of **Urine #5** (cc)..... _____
c. Has **Blood #5** been drawn? (1 = yes, 2 = no)..... _____

Separate the blood by centrifugation and place the serum in the corresponding vials. Aliquot urine into appropriate vials as well.

**Modification of Diet in Renal Disease Study
GFR Determination Worksheet Form**

23. Which of the following samples have been sent? (1 = yes, 2 = no)

- | | |
|--------------------------|--------------------------|
| a. Background Serum..... | h. Background Urine..... |
| b. Serum #0..... | i. Urine #1..... |
| c. Serum #1..... | j. Urine #2..... |
| d. Serum #2..... | k. Urine #3..... |
| e. Serum #3..... | l. Urine #4..... |
| f. Serum #4..... | m. Urine #5..... |
| g. Serum #5..... | |

24. Were there any problems obtaining blood samples or do you suspect any urine collection to be incomplete? (1 = yes, 2 = no).....

Comments: _____

25. a. Have samples been sent to central GFR lab? (1 = yes, 2 = no).....

b. Date samples sent to the Central GFR Laboratory..... / /

101. Certification number of MDRD Technician.....

102. Date form entered..... / /

103. Certification number of data entry person.....

Retain a copy of this form for your files. Send the original to the MDRD GFR Central Lab.
Please use MDRD Study mailing labels:

MDRD GFR Laboratory
Desk A101
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5042

**Modification of Diet in Renal Disease Study
CENTRAL LABORATORY BLOOD/URINE MAILING FORM**

This form is to be completed by the MDRD technician or study coordinator every month for the 24-hour urine collected (and in addition every second month for blood tests).

This form should be completed as blood and urine is required, whether samples are collected or not. See Manual of Operations, Chapter 3, for complete discussion of drawing blood, processing, packaging and shipment of containers.

Include a copy of this form, with the samples being shipped to the Central Biochemistry Lab. Complete, enter and transmit the form in the usual manner. Complete the form for all Required Procedures whether they were done or not.

QUESTION # INSTRUCTIONS

4. b. Visit type - B is baseline, F is follow-up, A is abbreviated follow-up for visits every 4th month after a stop point has been reached, and P should be used when blood work is being done at the special 2 week visit after a stop point. X is used for Study F blood work. Visit type K is for all Study C post stop point visits.
- c. Visit numbers are sequential as follows:
- | | |
|------------------------|--------------------------------|
| 0.0 = Baseline Visit 0 | |
| 1.0 = Baseline Visit 1 | 1.0 = Follow-up visit 1 |
| 2.0 = Baseline Visit 2 | 2.0 = Follow-up visit 2 |
| 3.0 = Baseline Visit 3 | 3.0 = Follow-up visit 3 |
| | 4.0 = Follow-up visit 4 (etc.) |

For blood work right after a stop point use 1.0 here.

If a second blood sample is sent after B3 for repeat albumin, label 3.9.

6. Indicate status of each applicable collection.
- a-b. A complete collection is defined as being between 23 1/2 and 24 1/2 hours. If it is not complete enter 3 and do not send samples to the lab. It is important to explain the reason why the blood or urine was not done (short collection, incomplete or spilled, patient fainted, or whatever the reason may be).
7. b. If the number of hours is zero, enter 0. If it is unknown, enter 99.
- d. Indicate the reason blood work was done. If due to action item, the form must indicate which tests need to be done by the CBL. This takes precedence over routine measures. The visit number alerts the CBL to which routine measures to do.
8. f. This question has been added.

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Rev. 5 10/4/90

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MDRD

Modification of Diet in Renal Disease Study Central Laboratory Blood/Urine Mailing Form

This form is to be completed every month for the 24-hour urine collected and every 2nd month for both blood and urine tests. Complete for all required tests.

FORM # 17

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date form completed..... / /
b. Visit Type.....
c. Visit Number.....
5. Type of Sample that should have been collected.....
1 = Blood
2 = Urine
3 = Both
6. a. Status of Blood Collection.....
1 = Blood collected
2 = Blood not collected due to short-term illness
3 = Blood not collected - other reason _____
b. Status of Urine Collection.....
1 = Urine collected
2 = Urine not collected due to short-term illness
3 = Urine not collected - other reason _____
7. a. Date blood drawn..... / /
b. How many hours was the patient fasting before blood was drawn?.....
c. Were medications (NSAIDS, cimetidine, trimethorprim, cephalosporins) appropriately withheld 48 hours prior to the test? (1 = yes, 2 = no)
(If not taking any medications, answer 1 = yes.)
d. Reason blood drawn.....
1 = Regularly scheduled
2 = 1 week after stop point
3 = Repeat B3 albumin for eligibility
4 = Repeat due to action item
specify: _____

Patient ID Number _____
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Form # 17
Page 2 of 2

**Modification of Diet in Renal Disease Study
Central Laboratory Blood/Urine Mailing Form**

- 8. a. Total volume of jug (urine + preservative) (ml)..... _____
- b. Volume of preservative alone _____
- c. Date urine collection completed..... ____/____/____
- d. Starting time (24-hour clock)..... ____ : ____
- e. Ending time (24-hour clock)..... ____ : ____
- f. Were medications withheld appropriately? (1 = yes, 2 = no)..... ____
(If not taking any medications, answer 1 = yes.)
- 9. a. Have samples been sent to the lab? (1 = yes, 2 = no)..... ____
- b. Date sent to central laboratory for analysis..... ____/____/____
- 101. Certification number of person completing this form..... _____
- 102. Date form entered..... ____/____/____
- 103. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study GFR Central Lab. Please use MDRD Study mailing labels:

MDRD Central Laboratories
Desk A101
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5042

Modification of Diet in Renal Disease Study
EKG MAILING FORM

This form is to be completed by the study coordinator. The original and one copy of the form should be sent with an original EKG (this must be 8 1/2 X 11 - do not send taped strips) and 1 copy of the strip to the DOC (who will deliver to the EKG Central Lab). Be sure to mark the patient ID number on the EKG tracing. Blank out patient name.

Complete this form for each required EKG, whether it was done or not.

Remember, post stop point Study C patients should be indicated by using visit type = K.

For DCC Use Only
Rev. 3 10/4/90

E ___
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Form # 18
Page 1 of 1

MDRD

Modification of Diet in Renal Disease Study EKG Mailing Form

This form is to be completed and a copy of the form should be made and sent with an original EKG to the DCC at B2 and annually starting at Follow-Up Visit #11. Complete for all required EKG's.

FORM # 18

1. Patient Identification Number.....
 2. Patient Name Code.....
 3. Clinical Center
 4. a. Date EKG done (or date scheduled, if not done)..... / /
 - b. Visit Type.....
 - c. Visit Number.....
 5. Was EKG performed? (1 = yes, 2 = no).....
 6. Standardization
- | | |
|---------------------|-------------|
| 1 = Standard | 4 = Other |
| 2 = One-half Normal | () |
| 3 = Twice normal | 9 = Unknown |
101. Date this form completed..... / /
 102. Certification number of person filling out this form
 103. Date form entered..... / /
 104. Certification number of data entry person

Retain a copy of this form for your files. Send the original and 1 copy to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
AMINO ACID MAILING FORM

This form is to be completed by the study coordinator and a copy sent with the sample to the Central Amino Acid Laboratory.

The Lab must know the number of hours fasting as well as the diet the patient is on. For further instructions, see the Manual of Operations, Amino Acid Section.

Complete this form for all required Amino Acid samples, whether collected or not.

An additional amino acid sample has been added. Diet K patients only at Follow-Up Visit 2.

QUESTION # INSTRUCTIONS

6. Enter 0 (zero) if patient did not fast. If unknown, enter 99.
8. If on Diet K and patient is not complying, still calculate the number of hours since keto acids were ingested. If 4 months,

$$30 \frac{\text{days}}{\text{month}} \times 24 \frac{\text{hours}}{\text{days}} \times 4 \text{ months} = 2880 \text{ hours.}$$

If the value is greater than 9999, then as always enter -1 and complete Form 24 with the correct value.

Modification of Diet in Renal Disease Study
LOCAL LAB QUALITY CONTROL FORM

This form will be used once a month at each Clinical Center. The form will contain the second measurements from submitting a duplicate sample to the local lab in the DETERMINATION 2 SECTION.

QUESTION # INSTRUCTIONS

5. DETERMINATION 2 should be completed with lab values from sending a duplicate sample through the local lab later that same day or on the next day.

Be sure that any necessary conversions in units are taken care of and the value entered is in the proper units.

For DCC Use Only
Rev. 1 9/1/88

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Modification of Diet in Renal Disease Study Local Lab Quality Control Form

This form is to be completed by each Clinical Center every month for quality control with duplicate samples on one patient. The first determination will be recorded on Form #6 with the local lab results. The duplicate sample results should be recorded here.

FORM # 20

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of visit.....
b. Visit Type.....
c. Visit Number.....
5. Serum Determination 2 (Duplicate sample)
Be very careful to make any appropriate unit conversions.
 - a. Date of analysis.....
 - b. Urea Nitrogen (mg/dl).....
 - c. Creatinine (mg/dl)
 - d. Calcium (mg/dl)
 - e. Magnesium (mg/dl) (check units).....
101. Date this form completed.....
102. Certification number of person filling out this form
103. Date form entered.....
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
CAP QUALITY CONTROL FORM

This form will be completed at each Clinical Center every four months from samples provided by the Central Lab. The data will be examined, and a report sent back to each Clinical Center. The tests should be done within 48 hours and the form sent promptly. If results are not sent in 96 hours, Central Biochemistry Lab personnel will call to inquire.

<u>QUESTION #</u>	<u>INSTRUCTIONS</u>
3a.	The sample number will be provided by the central lab. It is simply a sequential number of the CAP's sent out.
b.	If one or more measures are out of range, the central lab will send a second sample for you to repeat these measures. If this is the case, enter 1 = yes.
4.-5.	Run the sample through the local lab two times for Determination 1 and 2. Record the proper values as indicated on the form.
6.	Enter the method being used at the local lab. The complete coding list can be found here and in the Manual of Operations. Included here is the list of test methods/instrumentation. Every 4 months when CAP samples are to be run, this list will be sent to you. Take the list to your local laboratory liason. Have them indicate which method and instrument is currently in use. These are identified by a code letter for the "Method" and a two digit code number for the "instrument". If they indicate "other method" or "test not performed in this lab", use the appropriate letter code with "00" for the number code. This list must be completed every four months to be kept current. Your CAP data cannot be reviewed without this information.

Biochemistry's List of Test Methods/Instrumentation Codes

CALCIUM - SERUM (MG/DL)

- A. ALIZARIN
 - 01 Baker Centrifichem
 - 02 Baker Encore
 - 03 All Auto Chem Instr
- B. ARSENAZO III DYE
 - 01 Kodak Ektachem
 - 02 All Auto Chem Instr
- C. ATOMIC ABSORPTION
 - 01 All Auto Chem Instr
 - 02 All Atomic Absorp Spec
- D. CHLOROPHOSPHONAZO III
 - 01 All Auto Chem Instr
- E. CRESOLPHIHALEIN COMPLEXONE
 - 01 Abbott ABA 100
 - 02 Abbott ABA 200
 - 03 Abbott Spectrum
 - 04 Abbott VP
 - 05 American Dade Paramax
 - 06 American Mon. Parallel
 - 07 American Mon. KDA
 - 08 Baker Centrifichem
 - 09 Beckman Astra 4 & 8
 - 10 BM Diag. 8700/M
 - 11 Chemetrics II
 - 12 Coulter Dacos
 - 13 Dow
 - 14 Dupont ACA
 - 15 Electronuc Flexigem
 - 16 Electronuc Gemeni
 - 17 Electronuc Gemstar
 - 18 Gilford Impact 400, Etc.
 - 19 Gilford Sys 102, Etc.
 - 20 Gilford Sys 103, 202, 5
 - 21 Hitachi 705 (BMD)
 - 22 Hitachi 737 (BMD)
 - 23 IL Multistat III
 - 24 IL 508/504
 - 25 Kone Instruments
 - 26 Olympus Demand
 - 27 Roche Cobas
 - 28 Roche Cobas Mira
 - 29 Technicon RA 1000
 - 30 Technicon SMA 12/60
 - 31 Technicon SMAC
 - 32 All Auto Chem Instr
 - 33 All Manual Chem Instr
- F. METHYLTHYMOL BLUE
 - 01 IL Multistat III
 - 02 All Auto Chem Instr
- G. 00 OTHER METHOD, SPECIFY
- H. 00 TEST NOT PERFORMED
IN THIS LAB

CREATININE - SERUM (MG/DL)

- A. ALK PICRATE W/ LLOYDS
 - 01 Electronuc Gemeni
 - 02 All Auto Chem Instr
 - 03 All Chem Instr
- B. ALK PICRATE W/O LLOYDS
 - 01 Electronuc Gemeni
 - 02 Electronuc Gemstar
 - 03 Gilford Impact 400, Etc.
 - 04 Gilford Sys 102, Etc.
 - 05 Gilford Sys 103, 202, 5
 - 06 Manual, In House Reag.
 - 07 Olympus Demand
 - 08 Technicon RA 1000
 - 09 Technicon SMA 12/60
 - 10 Technicon SMAC
 - 11 All Auto Chem Instr
 - 12 All Manual Chem Instr
- C. ENZYMATIC
 - 01 Kodak Ektachem
 - 02 All Auto Chem Instr
- D. KINECTIC ALK. PICRATE
 - 01 Abbott ABA 100
 - 02 Abbott ABA 200
 - 03 Abbott Spectrum
 - 04 Abbott VP
 - 05 American Dade Paramax
 - 06 American Mon. Parallel
 - 07 American Monitor KDA
 - 08 Baker Centrifichem
 - 09 Beckman Astra 4 & 8
 - 10 Beckman Sp Const Analy
 - 11 BM Diag. 8700/M
 - 12 Chemetrics II
 - 13 Coulter Dacos
 - 14 Dupont ACA
 - 15 Electronuc Gemeni
 - 16 Electronuc Gemstar
 - 17 Gilford Impact 400, Etc.
 - 18 Gilford Sys 102, Etc.
 - 19 Gilford Sys 103, 202, 5
 - 20 Hitachi 705 (BMD)
 - 21 Hitachi 737 (BMD)
 - 22 IL Multistat III
 - 23 IL 508/504
 - 24 Kone Instruments
 - 25 Olympus Demand
 - 26 Roche Cobas
 - 27 Roche Cobas MIRA
 - 28 Technicon RA 1000
 - 29 All Auto Chem Instr
- E. 3, 5 DINITRO BENZOIC
 - 01 Ames Seralyzer
- F. 00 OTHER METHOD, SPECIFY
- G. 00 TEST NOT PERFORMED
IN THIS LAB

Biochemistry's List of Test Methods/Instrumentation Codes

MAGNESIUM - SERUM (MG/DL)

- A. ATOMIC ABSORPTION
 - 01 IL AA Spectro
 - 02 Perkin-Elmer
 - 03 All Auto Chem Instr
- B. CALMAGITE
 - 01 Abbott VP
 - 02 American Dade Paramax
 - 03 American Mon. Parallel
 - 04 American Monitor
 - 05 American Monitor KDA
 - 06 Baker Centrifichem
 - 07 Electronuc Flexigem
 - 08 Electronuc Gemeni
 - 09 Gilford Impact 400, Etc.
 - 10 Gilford Sys 102, Etc.
 - 11 Hitachi 705 (BMD)
 - 12 Olympus Demand
 - 13 Pierce
 - 14 Roche Cobas
 - 15 Technicon RA 1000
 - 16 All Auto Chem Instr
 - 17 All Manual Chem Instr
- C. COLORIMETRIC - METHYLTHY
 - 01 Dupont ACA
 - 02 All Auto Chem Instr
- D. MAGNON
 - 01 Gilford Impact 400, Etc.
 - 02 All Auto Chem Instr
- E. 00 OTHER METHOD, SPECIFY
- F. 00 TEST NOT PERFORMED IN THIS LAB

UREA - SERUM (MG/DL)

- A. CONDUCTIVITY RATE
 - 01 Beckman Astra 4 & 8
 - 02 Beckman Sp Const Analy
 - 03 All Auto Chem Instr
- B. DIACETYL MONOXIME
 - 01 Dow
 - 02 Technicon SMA 12/60
 - 03 Technicon SMAC
 - 04 All Auto Chem Instr
 - 05 All Manual Chem Instr
- C. O-PHTHALALDEHYDE
 - 01 American Mon. Parallel
 - 02 American Monitor KDA
 - 03 Ames Seralyzer
 - 04 All Auto Chem Instr
 - 05 All Manual Chem Instr
- D. UREASE HYDROLYSIS
 - 01 Beckman Astra 4 & 8
 - 02 Electronuc Gemeni
 - 03 Olympus Demand
 - 04 All Auto Chem Instr

UREA - SERUM (CONT)

- E. UREASE INDOPHENOL
 - 01 All Auto Chem Instr
 - 02 All Manual Chem Instr
- F. UREASE QUINOLINIUM
 - 01 Kodak DT 60
 - 02 Kodak Ektachem
 - 03 All Auto Chem Instr
- G. UREASE WITH GLDH
 - 01 Abbott ABA 100
 - 02 Abbott ABA 200
 - 03 Abbott Spectrum
 - 04 Abbott VP
 - 05 American Dade Paramax
 - 06 Baker Centrifichem
 - 07 Beckman Astra 4 & 8
 - 08 BM Diag. 8700/M
 - 09 Chemetrics
 - 10 Chemetrics II
 - 11 Coulter Dacos
 - 12 Dupont ACA
 - 13 Electronuc Flexigem
 - 14 Electronuc Gemeni
 - 15 Electronuc Gemstar
 - 16 Gilford Impact 400, Etc.
 - 17 Gilford Sys 102, Etc.
 - 18 Gilford Sys 103, 202, 5
 - 19 Hitachi 705 (BMD)
 - 20 Hitachi 737 (BMD)
 - 21 IL Multistat III
 - 22 IL 508/04
 - 23 Kone Instruments
 - 24 Olympus Demand
 - 25 Roche Cobas
 - 26 Roche Cobas MIRA
 - 27 Technicon RA 1000
 - 28 All Auto Chem Instr
 - 29 All Manual Chem Instr
- H. 00 OTHER METHOD, SPECIFY
- I. 00 TEST NOT PERFORMED IN THIS LAB

Signature of Lab Director

Date

Institution

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For DCC Use Only
Rev. 2 10/15/88

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Form # 21
Page 1 of 2



**Modification of Diet in Renal Disease Study
CAP QC Form**

This form is to be completed by each Clinical Center every four months for quality control on CAP samples sent from the Central Biochemistry Laboratory.

FORM # 2 1

1. Clinical Center ___

2. Date specimens received from Central Biochemistry Lab ___ / ___ / ___

3. a. Sample Number..... ___

b. Was this a repeat measurement? (1 = yes, 2 = no)..... ___

4. Serum Determination 1

Be very careful to make any appropriate unit conversions.

a. Date of analysis..... ___ / ___ / ___

b. Urea Nitrogen (mg/dl)..... ___

c. Creatinine (mg/dl)..... ___

d. Calcium (mg/dl)..... ___

e. Magnesium (mg/dl) (check units)..... ___

5. Serum Determination 2

a. Date of analysis..... ___ / ___ / ___

b. Urea Nitrogen (mg/dl)..... ___

c. Creatinine (mg/dl)..... ___

d. Calcium (mg/dl)..... ___

e. Magnesium (mg/dl) (check units)..... ___

6. Methods

See Coding List in Manual of Operations.

a. Urea Nitrogen..... ___

b. Creatinine..... ___

c. Calcium..... ___

d. Magnesium..... ___

**Modification of Diet in Renal Disease Study
CAP QC Form**

101. Date this form completed....._ _ / _ _ / _ _
102. Certification number of person filling out this form _ _ _ _ _
103. Date form entered....._ _ / _ _ / _ _
104. Certification number of data entry person _ _ _ _ _

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

**Modification of Diet in Renal Disease Study
CENTRAL LAB QC ID MATCHING FORM**

This form is to be completed when the Clinical Center sends a patient's sample to the Central Biochemistry Lab, Central GFR Lab, Central Amino Acid Lab, or Central EKG lab in duplicate for quality control with one sample labeled with the patient ID and the other labeled with the Center's quality control ID. DO NOT send a copy of this form to the Central Lab. Transmit and send promptly to the DCC only.

This form is used also for split anthropometry, Blood Pressure, and QWB samples. Always use the "real" patient ID number.

For GFR: Do not transmit Form 22 until you receive the original "real" GFR report back from the lab indicating the GFR was OK.

For DCC Use Only
Rev. 5/6/91

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Modification of Diet in Renal Disease Study Central Lab QC ID Matching Form

This form is to be completed when the Clinical Center sends a patient's sample to the Central Biochemistry Lab, GFR Lab, or the Central Amino Acid Lab in duplicate, for quality control. Also complete when anthropometry or blood pressure QC is done locally.

FORM # 2 2

1. Patient Identification Number (whose sample was sent in duplicate) _____
2. Patient Name Code..... _____
3. Clinical Center..... _____
4. a. Visit Type..... _____
b. Visit Number..... _____
c. Type of QC..... _____
 1 = Amino acid sample 5 = Anthropometry
 2 = Central Biochemistry sample 6 = Blood Pressure
 3 = GFR samples 7 = QWB
 4 = EKG sample
5. Date of patient visit at which blood was drawn..... ___/___/___
6. Date when the 24-hour urine was collected..... ___/___/___
7. Date GFR samples collected..... ___/___/___
8. Date EKG done..... ___/___/___
9. Date Anthropometry done..... ___/___/___
10. Date Blood Pressure done..... ___/___/___
11. Date of visit associated with QWB (F27Q04A)..... ___/___/___
101. Date this form completed..... ___/___/___
102. Certification number of person filling out this form..... _____
103. Date form entered..... ___/___/___
104. Certification number of data entry person..... _____

**Modification of Diet in Renal Disease Study
ACTION ITEM RESPONSE FORM**

This form is to be completed every month that a patient reaches an action item. It is to be entered into Datalex Entrypoint 90. Comment carefully with key words, doses, repeats etc...

If the response to an action item is to follow the protocol exactly, you do not need to complete the text portion of the question.

Do not worry about having question 15 on Form 5 correspond with the number of action item Form 23's that are completed.

This then brings up the question of how to identify the visit type and number on the Form 23 for any given action item. Since you may not have all the central lab data from a particular visit (i.e. Follow-up #3), you will not be able to complete the entire Form 23 (or all the Form 23's needed) until after the F-3.0. You may choose to complete it at the patients next F-4.0 with the appropriate visit number of F-3.0 which is what the action item flow sheet would also reflect.

For DCC Use Only
Rev. 3 3/27/90

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Modification of Diet in Renal Disease Study Action Item Response Form

This form is to be completed once for each visit when at least one action item has occurred. It should not be completed until complete documentation of the occurrence of action items is available and a course of treatment has been determined.

FORM # 23

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of visit..... / /
- b. Visit type.....
- c. Visit number.....

The following is a coding list for the questions asked below.

- | | |
|---------------------------------------|--|
| 1 = GFR (Study A Only) | 17 = Persistent Four Month Mean UNA Out-of-Range |
| 2 = Weight Loss | 18 = Low Serum Phosphorus |
| 3 = Weight Gain | 19 = Low Serum Calcium |
| 4 = Overweight Diabetic | 20 = High Serum Calcium |
| 5 = High Blood Pressure | 21 = High Serum Potassium |
| 6 = Persistent High Blood Pressure | 22 = Low Serum Bicarbonate |
| 7 = Low Blood Pressure Symptoms | 23 = Low Serum Magnesium |
| 8 = Persistent Low Blood Pressure | 24 = Low Serum Iron |
| 9 = Declining Serum Albumin | 25 = High Serum Cholesterol |
| 10 = Low Serum Albumin | 26 = High Serum LDL Cholesterol |
| 11 = Declining Serum Transferrin | 27 = High Serum Triglycerides |
| 12 = High Serum Phosphorus | 28 = Low Vitamin A |
| 13 = Very High Serum Phosphorus | 29 = 4 Month Aminogram (14b) |
| 14 = Absent Alloisoleucine | 30 = Persistent Aminogram (14c) |
| 15 = Monthly UNA Out-of-Range | |
| 16 = Four Month Mean UNA Out-of-Range | |

Below list all action items which occurred, and the steps being taken to resolve them. Please be specific.

5. a. Action item code number
- b. Was this action handled according to the protocol? (1 = yes, 2 = no)
- c1. Steps: _____
- c2. _____
- c3. _____

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**Modification of Diet in Renal Disease Study
Action Item Response Form**

- 6. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
- 7. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
- 8. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
- 9. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
- 10. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____

Patient ID Number _____
Rev. 3 3/27/90

Form # 23
Page 3 of 3

**Modification of Diet in Renal Disease Study
Action Item Response Form**

- 101. Date this form completed..... ____/____/____
- 102. Certification number of person filling out this form
- 103. Date form entered..... ____/____/____
- 104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

**Modification of Diet in Renal Disease Study
DATA OUT-OF-RANGE FORM**

This form is to be completed by the Study Coordinator for each data item that is not within a predefined item range, thus could not be entered in Datalex.

QUESTION # INSTRUCTIONS

4. Enter date of form with out of range value. Refer to next page for correct date for each form. Enter Visit Type and Number on that form. If form does not refer to specific visit type and number, leave these spaces blank.

Remember that a -1 must appear on the actual form in place of the value you could not enter.

5. The form number should be entered. All items listed following must pertain to this form.
- 6a. The item number must be entered. For instance, on Form #04, Page 2, the item number for current employment status is:
Q14B
The item number for date form completed is
Q101

- 6b. Enter decimal point when needed in a separate space.

(Example: 0 3 5 . 2).

For 24-hour clock values:

(Example: 0 9 : 3 0).

For dates:

(Example: 1 0 1 8 8 8).

When trying to indicate to blank out a field enter

(Example: B L A N K).

When trying to indicate deletion of a form enter

(Example: D E L E T E).

- 7.-8. Complete as in 6a and 6b.

If more than three items on a particular form are out-of-range, you should complete a second form 24 for those subsequent to the 3rd.

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Modification of Diet in Renal Disease Study
DATA OUT-OF-RANGE FORM

DATE OF VISIT

Form 01	Date form completed (item 101)
Form 02	Date form completed (item 101)
Form 03	Date of screening (visit item 4a)
Form 04	Date of visit (item 5a)
Form 05	Date of this clinic visit (item 4a)
Form 06	Date of this clinic visit (item 4a)
Form 07	Date form completed (item 101)
Form 08	Date form completed (item 101)
Form 09	Date of randomization (item 6)
Form 10	Date of medical attention (item 4a)
Form 11	Date stop point is declared (item 6)
Form 12	Date of follow-up visit (item 4a)
Form 13	Date of visit (item 4a)
Form 14	Date of last visit (item 4a)
Form 15	Date of death (item 4)
Form 16	Date of GFR test (item 4a)
Form 17	Date form completed (item 4a)
Form 18	Date EKG done (item 4a)
Form 19	Date of visit (item 4a)
Form 22	Date form completed (item 101)
Form 23	Date of visit (item 4a)
Form 24	Date of form (item 4a)
Form 25	Date of form (item 4a)
Form 26	Date of visit (item 4a)
Form 27	Date of visit (item 4a)
Form 28	Date of visit (item 4a)
Form 29	Date of visit (item 4)
Form 30	Date of transfer (item 6)
Form 31	Date form completed (item 101)
Form 32	Date urine collected (item 5a)
Form 33	Date blood collected (item 5a)
Form 34	Date specimens received from Central GFR Lab (item 1)
Form 35	Date of EKG tracing (item 4a)
Form 36	Date sample drawn (item 4a)
Form 37	Date of randomization (item 4)
Form 38	Date of review (item 7)
Form 40	Date of stop point review (item 5)
Form 41	Date of death (item 4)
Form 42	Date of assay (item 5a)
Form 46	Date of visit (item 4a)
Form 47	Date of contact (item 4a)
Form 48	Date of visit (item 4a)
Form 49	Date of review (item 6)
Form 50	Date form completed (item 101)
Form 51	Date of visit (item 4a)
Form 65	Date of visit (item 4a)
Form 66	Date form completed (item 101)

Modification of Diet in Renal Disease Study
DATA OUT-OF-RANGE FORM

DATE OF VISIT

Form 71	Date of visit (item 4a)
Form 72	Date of visit (item 4a)
Form 73	Date of this visit (item 5a)
Form 74	Date of visit (item 4a)
Form 76	Date of visit or contact (item 4a)
Form 77	Date of visit (item 4a)
Form 78	Date form given to patient (item 4a)
Form 79	Date of visit (item 4a)

For DCC Use Only
Rev. 2 10/15/88

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Modification of Diet in Renal Disease Study Data Out-of-Range Form

This form is to be completed for each data item that is not within a pre-defined value range, and thus could not be entered in Entrypoint 90.

FORM # 24

1. Patient Identification Number.....
 2. Patient Name Code.....
 3. Clinical Center
 4. a. Date of form with out-of-range value..... / /
 - b. Visit Type.....
 - c. Visit Number.....
 5. Form Number
 6. a. Item Number 1
 - b. Correct Data Value (Enter decimal point if needed).....
- NOTE: the following items must occur on the same form as in item 5.**
7. a. Item Number 2.....
 - b. Correct Data Value (Enter decimal point if needed).....
 8. a. Item Number 3.....
 - b. Correct Data Value (Enter decimal point if needed).....
101. Date this form completed..... / /
 102. Certification number of person filling out this form
 103. Date form entered..... / /
 104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
DATA CHANGE FORM

This form is to be completed by the Study Coordinator when the Clinical Center identifies data that needs to be changed, added or deleted.

QUESTION # INSTRUCTIONS

4. Enter date of form. Refer to next page for correct date for each form. Enter Visit Type and Number on that form. If form does not refer to specific visit type and number, leave these spaces blank.
5. The form number should be entered. Each Form #25 can be used for up to 3 data changes on a form. If more than one form has changes to be made, then a Form # 25 for each of those forms must be completed.
- 6a. The item number must be entered. For instance, on Form #04, Page 2, the item number for current employment status is
Q14B
The item number for date form completed is
Q101

- 6b. Enter decimal point when needed in a separate space
(Example: 0 3 5 . 2 1)

OR

For 24-hour clock values:
(Example: 0 9 : 3 0)

for dates:
(Example: 1 0 1 8 8 8)

do not enter '/'s.

When trying to indicate to blank out a field enter

(Example: B L A N K).

When trying to indicate deletion of a form enter

(Example: D E L E T E).

- 7.-8. Complete as in items 6a and 6b.

If more than three items on a particular form need to be changed, you should complete a second form 25 for those subsequent to the 3rd change.

Modification of Diet in Renal Disease Study
DATA CHANGE FORM

DATE OF VISIT

Form 01 Date form completed (item 101)
Form 02 Date form completed (item 101)
Form 03 Date of screening (visit item 4a)
Form 04 Date of visit (item 5a)
Form 05 Date of this clinic visit (item 4a)
Form 06 Date of this clinic visit (item 4a)
Form 07 Date form completed (item 101)
Form 08 Date form completed (item 101)
Form 09 Date of randomization (item 6)
Form 10 Date of medical attention (item 4a)
Form 11 Date stop point is declared (item 6)
Form 12 Date of follow-up visit (item 4a)
Form 13 Date of visit (item 4a)
Form 14 Date of last visit (item 4a)
Form 15 Date of death (item 4)
Form 16 Date of GFR test (item 4a)
Form 17 Date form completed (item 4a)
Form 18 Date EKG done (item 4a)
Form 19 Date of visit (item 4a)
Form 22 Date form completed (item 101)
Form 23 Date of visit (item 4a)
Form 24 Date of form (item 4a)
Form 25 Date of form (item 4a)
Form 26 Date of visit (item 4a)
Form 27 Date of visit (item 4a)
Form 28 Date of visit (item 4a)
Form 29 Date of visit (item 4)
Form 30 Date of transfer (item 6)
Form 31 Date form completed (item 101)
Form 32 Date urine collected (item 5a)
Form 33 Date blood collected (item 5a)
Form 34 Date specimens received from Central GFR Lab (item 1)
Form 35 Date of EKG tracing (item 4a)
Form 36 Date sample drawn (item 4a)
Form 37 Date of randomization (item 4)
Form 38 Date of review (item 7)
Form 40 Date of stop point review (item 5)
Form 41 Date of death (item 4)
Form 42 Date of assay (item 5a)
Form 46 Date of visit (item 4a)
Form 47 Date of contact (item 4a)
Form 48 Date of visit (item 4a)
Form 49 Date of review (item 6)
Form 50 Date form completed (item 101)
Form 51 Date of visit (item 4a)

Modification of Diet in Renal Disease Study
DATA CHANGE FORM

DATE OF VISIT

Form 65	Date of visit (item 4a)
Form 66	Date form completed (item 101)
Form 71	Date of visit (item 4a)
Form 72	Date of visit (item 4a)
Form 73	Date of this visit (item 5a)
Form 74	Date of visit (item 4a)
Form 76	Date of visit or contact (item 4a)
Form 77	Date of visit (item 4a)
Form 78	Date form given to patient (item 4a)
Form 79	Date of visit (item 4a)

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Modification of Diet in Renal Disease Study Data Change Form

This form is to be completed for each data item other than those in the query system that the clinical center needs changed, added or deleted in the database.

FORM # 25

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of form with incorrect data / /
- b. Visit Type.....
- c. Visit Number.....
5. Form number.....
6. a. Item number 1
- b. Correct Data Value (Enter decimal point if needed).....
- Note: the following items must occur on the same form as in Item 5.**
7. a. Item number 2
- b. Correct Data Value (Enter decimal point if needed).....
8. a. Item number 3
- b. Correct Data Value (Enter decimal point if needed).....
101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Date form entered..... / /
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

**Modification of Diet in Renal Disease Study
PATIENT SYMPTOM FORM**

This form should be completed by the patient at each monthly visit. The study coordinator should complete items 1-4 and 101-104 as usual. For stop point patients it should be completed annually.

In Datalex, Severity is entered using a coding scheme. If mild is checked, enter a 1 in the space provided on the Datalex screen. If moderate is checked, enter a 2. If severe is checked, enter a 3. These instructions are provided only on the 2nd screen of the Datalex application.

The number of days in past month should be from 0-31. Not since the last visit.

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Modification of Diet in Renal Disease Study Patient Symptom Form

Thinking back on the last month, mark the number of days in which you have felt each of the symptoms listed below. If you never felt the symptom then enter a zero in the space. Do not leave it blank. Next, put a check under the column indicating the severity of each of the symptoms that was felt. Leave severity blank if symptom not felt.

FORM # 26

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of visit.....
- b. Visit Type
- c. Visit Number.....

	Number of Days in Past Month (Enter 0 if None)	SEVERITY		
		Mild	Moderate	Severe
5. a bad taste in your mouth?	___	___	___	___
6. loss of appetite?	___	___	___	___
7. nausea or being sick to your stomach?	___	___	___	___
8. vomiting?	___	___	___	___
9. heartburn?	___	___	___	___
10. abdominal bloating or gas?	___	___	___	___
11. diarrhea?	___	___	___	___
12. constipation?	___	___	___	___
13. hiccoughs?	___	___	___	___
14. itching?	___	___	___	___
15. hives or another type of rash?	___	___	___	___
16. easy bruising or bleeding?	___	___	___	___
17. lack of pep and energy?	___	___	___	___

**Modification of Diet in Renal Disease Study
 Patient Symptom Form**

	Number of Days in Past Month (Enter 0 if None)	SEVERITY		
		Mild	Moderate	Severe
18. tiring easily, weakness?	___	___	___	___
19. muscle cramps?	___	___	___	___
20. numbness and tingling in your hands and feet?	___	___	___	___
21. feeling faint when you stand up?	___	___	___	___
22. difficulty in falling or staying asleep?	___	___	___	___
23. falling asleep during the day?	___	___	___	___
24. feeling irritable?	___	___	___	___
25. decreased alertness?	___	___	___	___
26. forgetfulness?	___	___	___	___
27. blurred vision?	___	___	___	___
28. Other unexpected symptoms? (20 characters maximum)(_____)	___	___	___	___

- 101. Date this form completed by patient / /
- 102. Certification number of person reviewing this form
- 103. Date form entered..... / /
- 104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
 Department of Biostatistics & Epidemiology
 The Cleveland Clinic Foundation
 9500 Euclid Avenue
 Cleveland, Ohio 44195-5196

MDRD Form 27

Quality of Well Being Scale

"The holder of the copyright for the "Quality of Well-being (QWB) Scale" did not grant permission to reproduce this form. Persons interested in reviewing copies of this form should visit the following website to obtain the document:
<http://qwbsa.ucsd.edu/qwbsa/>"

MDRD Form 28

Symptom CheckList

"The holder of the copyright for the "Symptom CheckList" did not grant permission to reproduce this form. Persons interested in reviewing copies of this form should visit the following website to obtain the document:
[http://www.pearsonassessments.com/scl90.aspx.](http://www.pearsonassessments.com/scl90.aspx)"

Modification of Diet in Renal Disease Study
ECONOMIC INFORMATION FORM

This form should be completed at the Screening Visit and annually thereafter for patients continuing on in the study.

This health insurance information requested is for HCFA billing purposes. Additional information regarding billing is located in the Manual of Operations in the chapter on Billing.

Complete the form and retain a copy for your Center's records. Send the original to HCFA.

The subscriber is the person purchasing the policy. If no number is given, it is usually the social security number.

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Modification of Diet in Renal Disease Study Economic Information Form

This form should be completed at the Screening visit and annually thereafter. The original should be sent to HCFA.

FORM # 29

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. Date of visit..... / /
5. a. Name of patient
- b. Social Security Number..... - - - - -
6. Does the patient have health insurance? (1 = yes, 2 = no).....

If NO, skip to Item 7.

If YES, complete "(1)" through "(4)" for each insurance plan, "A" through "C".

- A. 1. Type of Plan.....
- 1 = Employee Group Plan
 - 2 = Individual Plan
 - 3 = Other Group Plan (_____)
2. Name of insurance company (not employer)
- _____
3. Subscriber
- a. Name _____
 - b. Number _____
 - c. Is the patient the subscriber? (1 = yes, 2 = no).....
4. Is this an HMO (health maintenance organization) type of coverage (i.e., patient limited to a specific set of health care providers)? (1 = yes, 2 = no).....

**Modification of Diet in Renal Disease Study
Economic Information Form**

If more than one insurance plan, continue. Otherwise skip to Item 7.

- B. 1. Type of Plan.....
1 = Employee Group Plan
2 = Individual Plan
3 = Other Group Plan (_____)
2. Name of insurance company (not employer)

3. Subscriber
a. Name _____
b. Number _____
c. Is the patient the subscriber? (1 = yes, 2 = no).....
4. Is this an HMO (health maintenance organization) type of coverage (i.e., patient limited to a specific set of health care providers)? (1 = yes, 2 = no).....

If more than two insurance plans, continue. Otherwise skip to Item 7.

- C. 1. Type of Plan.....
1 = Employee Group Plan
2 = Individual Plan
3 = Other Group Plan (_____)
2. Name of insurance company (not employer)

3. Subscriber
a. Name _____
b. Number _____
c. Is the patient the subscriber? (1 = yes, 2 = no).....
4. Is this an HMO (health maintenance organization) type of coverage (i.e., patient limited to a specific set of health care providers)? (1 = yes, 2 = no).....
7. If the patient has not indicated Medicare or Medicaid as a part of his/her health insurance coverage in item 6 above, ask the following:
- a. Has the patient applied for Medicare? (1 = yes, 2 = no).....
- b. Has the patient applied for Medicaid? (1 = yes, 2 = no).....
8. a. Is the patient receiving "Disability income" from Social Security? (1 = yes, 2 = no).....
- b. If yes, for how many months?.....
- c. If yes, how much per month.....\$ _____

Patient ID Number _____
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Form # 29
Page 3 of 3

**Modification of Diet in Renal Disease Study
Economic Information Form**

101. Date this form completed..... _____/_____/_____
102. Certification number of person filling out this form _____
103. Date form entered..... _____/_____/_____
104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the Health Care Finance Administration. Please use MDRD Study mailing labels:

Health Care Finance Administration
Office of Research and Demonstrations
P.O. Box 11972
Baltimore, Maryland 21207-0972
ATTENTION: Research and Demonstrations
Systems Support MDRD STUDY

Modification of Diet in Renal Disease Study

TRANSFER FORM

This form is to be completed by the Study Coordinator whenever a patient transfers from another Clinical Center's care. The destination Center should complete this form.

Contact the original Clinical Center to coordinate date of transfer and other pertinent patient information.

QUESTION #

INSTRUCTIONS

- | | |
|-------|---|
| 1.-3. | Identify the patient by the new sequential identification number and name code. |
|-------|---|

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Form # 30
Page 1 of 1

MDRD
Modification of Diet in Renal Disease Study
Transfer Form

This form is to be completed whenever a patient transfers from another Clinical Center's care. The destination center should complete this form.

FORM # 30

1. New Patient Identification Number
2. New Patient Name Code
3. Clinical Center (destination)
4. Clinical Center (original)
5. Original Patient Identification Number.....
6. Date of transfer..... / /
101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Date form entered..... / /
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
STUDY C ASSIGNMENT

This form is to be completed by the Study Coordinator when a patient is eligible for Study C.

QUESTION # INSTRUCTIONS

4. The patient must sign a new informed consent for Study C, agreeing to begin Diet K. If the patient refuses, enter 2 = no.

- 5-6. Complete keto acid prescription. Dietitian should do calculations - a report will not be generated. Do not complete Form 71 and only complete Form 72 if other nutrients are changing. Do not complete Protein Prescription section of Form 72.

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Modification of Diet in Renal Disease Study Study C Assignment

This form is to be completed by the Clinical Center when a patient enters Study C.

FORM # **31**

1. Patient Identification Number.....

2. Patient Name Code.....

3. Clinical Center

4. a. Has the patient signed the Study C Informed Consent Form? (1 = yes, 2 = no)

b. Date form sent to Data Coordinating Center..... / /

5. **Keto Acid Tablets Prescription**--For participants on Diet K who are on prescribed **tablets**. (Daily dose = 0.28 gm per kg Standard Body Weight. One tablet contains 0.93 gm keto acids.) If not prescribed, enter "0".

a. Total Number of Keto Acid Tablets Prescribed Daily

Distribute tablets based roughly on calorie distribution of meals:

b. Number of tablets at morning meal

c. Number of tablets at midday meal

d. Number of tablets at evening meal

6. **Keto Acid Packets Prescription**--For participants on Diet K who are on prescribed **packets**. (Daily dose = one packet (2.8 gm) per 10 kg Standard Body Weight.) If not prescribed, enter "0".

a. Total Number of Keto Acid Packets Prescribed Daily

(See Study Diet Prescription Report)

Distribute packets based roughly on calorie distribution of meals:

b. Number of packets at morning meal.....

c. Number of packets at midday meal

d. Number of packets at evening meal.....

101. Date this form completed..... / /

102. Certification number of person filling out this form.

103. Date form entered..... / /

104. Certification number of data entry person

Modification of Diet in Renal Disease Study
CENTRAL BIOCHEMISTRY LAB 24-HOUR URINE REPORT FORM

This form will be completed by Central Lab personnel. The data will be entered and a computer generated report will be sent to the Clinical Centers.

QUESTION # INSTRUCTIONS

- 4a. Visit types as usual are B for baseline, F for follow-up, A for abbreviated follow-up, and X for Study F, to indicate a urine collection right after a stop point is reached.
6. The answer should be carefully copied from the mailing form accompanying the sample. If the answer is yes, EPI will not be used for analysis.
7. a. pH: If the pH is ≥ 5 , do not report results.

	<u>Units</u>	<u>Allowable Range</u>
b. Creatinine	mg/day	300 - 4000
c. Urea Nitrogen	g/day	1.0 - 40.0
d. Protein	g/day	0.01 - 16.00
e. Phosphorus	mg/day	70 - 3000
f. Volume	ml	≥ 100
h. Sodium	mEq/day	10 - 500
i. Potassium	mEq/day	5 - 250

After FU 8, urine protein collected every 4 months.

**Modification of Diet in Renal Disease Study
Central Biochemistry Lab Form
24-Hour Urine Report**

8. Comments to clinical center:

9. Comments for internal purposes:

10. Did the laboratory discover any difficulties in the receipt of this sample? (1 = yes, 2 = no) ... _____

If no, skip to Item 12.
If yes, continue.

11. Which of the following problems were noted by the central lab?

For the following (1 = yes, 2 = no)

- a. Clerical problems with the data forms accompanying the sample..... _____
- b. Information on the label of the tube incomplete or unsatisfactory..... _____
- c. Sample leakage..... _____
- d. Quantity of sample insufficient..... _____
- e. Incorrect type of sample..... _____
- f. Other (_____)..... _____

12. a. Has afterthought urine been received and stored? (1 = yes, 2 = no)..... _____

b. Location code 1..... _____

c. Amount (ml)..... _____

d. Location code 2..... _____

e. Amount (ml)..... _____

101. Date this form completed..... ____/____/____

102. Certification number of person filling out this form..... _____

103. Lab director's signature..... _____

104. Certification number of lab director..... _____

105. Has form been signed by lab director? (1 = yes, 2 = no)..... _____

106. Date form entered..... ____/____/____

107. Certification number of data entry person..... _____

**Modification of Diet in Renal Disease Study
CENTRAL BIOCHEMISTRY LAB FORM
BLOOD ANALYSIS REPORT**

This form will be completed by Central Lab personnel. The data will be entered and a computer generated report will be sent to the Clinical Centers.

QUESTION # INSTRUCTIONS

- 4b. Visit type. As usual, use a P 1.0 to indicate blood work right after a stop point. If blood work is repeated between visits use xx.1 to indicate.

- 7a. Number of hours fasting. If zero, enter a zero. If unknown, enter 99.

- 9. Enter the Transferrin value in milligrams per deciliter. The allowable range for data entry is 140- 470.

- 10. Enter the Albumin value in grams per deciliter. The allowable range for data entry is 2.0-6.0.

- 11. Enter the Serum Phosphorus value in grams per deciliter. The allowable range is 1.0 - 10.0.

- 12. Enter the Serum Creatinine value in milligrams per deciliter. This data will be used for calculation of clearances. The allowable range for data entry is 0.1-15.0

- 13. Enter the Serum Urea Nitrogen value in milligrams per deciliter. This data will be used for calculation of clearances. The allowable range for data entry is 10-180.

- 15.-18. Enter each of the lab measurements in the appropriate units. Allowable ranges for data entry are as follows:

	<u>Units</u>	<u>Allowable Range</u>
Uric Acid	mg/dl	3.0 - 12.0
Bilirubin	mg/dl	0.1 - 2.0
LDH	Iu/L	50 - 400
SGOT	Iu/L	3 - 100

- 20. a. Enter the Triglyceride value in milligrams per deciliter. Allowable range is 10 - 1000.

- b. Enter the Total Serum Cholesterol value in milligrams per deciliter. Allowable range is 100 - 600.

Modification of Diet in Renal Disease Study
CENTRAL BIOCHEMISTRY LAB FORM
BLOOD ANALYSIS REPORT

QUESTION # INSTRUCTIONS

- c. Enter the HDL Cholesterol value in milligrams per deciliter. Allowable range is 10 - 150.
 - d. If the Triglyceride value is greater than 400, lab personnel measure LDL Cholesterol directly. If Triglyceride value is less than or equal to 400, LDL will be calculated.
 - e.-h. Further lipid analyses results done annually.
21. a. Enter a 1 if the afterthought 5 milliliter serum sample has been received and stored. Enter a 2 if not, and skip to item 19.
- b.-e. Enter the location and amount of the split sample.
23. The method to be used for Hemoglobin A_{1c} is HPLC. The value should be recorded as a percentage, to the nearest tenth. The allowable range for data entry is 3.0-15.0.

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Form # 33
Page 1 of 3



**Modification of Diet in Renal Disease Study
Central Biochemistry Lab Form
Blood Analysis Report**

This form is to be completed for each patient's blood measurements by the Central Biochemistry Laboratory personnel.

FORM # 33

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Visit Type.....
b. Visit Number.....
5. a. Date blood samples drawn..... / /
b. Date blood received at Central GFR Lab / /
c. Date blood received at Biochemistry Lab / /
6. Did the patient have a short-term illness when blood was drawn? (1 = yes, 2 = no).....
7. a. Number of hours patient was fasting prior to blood being drawn (From FORM #17) ____
b. Were medications appropriately withheld 48 hours prior to blood test?
(1 = yes, 2 = no)
8. Date Routine Serum analyses completed at the Central Lab / /
9. Transferrin (mg/dl) (potential action item)
10. Albumin (g/dl) (potential action item).....
11. Phosphorus (mg/dl) (potential action item).....
12. Creatinine (mg/dl)
13. Urea Nitrogen (mg/dl).....
14. Date liver function test analyses completed at the Central Lab..... / /
15. Uric Acid (mg/dl).....
16. Bilirubin (mg/dl).....
17. LDH (IU/l).....
18. SGOT (IU/l).....

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**Modification of Diet in Renal Disease Study
Central Biochemistry Lab Form
Blood Analysis Report**

19. Date lipid analyses completed at the Central Lab.....__ __/__ __/__ __

20. Lipid Profile

a. Triglycerides (mg/dl).....__ __

b. Total Serum Cholesterol (mg/dl).....__ __

c. HDL Serum Cholesterol (mg/dl)__ __

d. LDL Serum Cholesterol (mg/dl) (potential action item)__ __

e. HDL₂ (mg/dl).....__ __

f. HDL₃ (mg/dl).....__ __

g. Apolipoprotein A₁ (mg/dl).....__ __

h. Apolipoprotein B (mg/dl).....__ __

21. a. Has afterthought serum been received and stored? (1 = yes, 2 = no).....__

b. Location code 1.....__ __

c. Amount (ml).....__ __

d. Location code 2.....__ __

e. Amount (ml).....__ __

22. Date Hemoglobin A₁C analysis completed at the Central Lab.....__ __/__ __/__ __

23. Hemoglobin A₁C (HPLC Method) (%).....__ __

24. Comments to clinical center:

25. Comments for internal purposes:

**Modification of Diet in Renal Disease Study
Central Biochemistry Lab Form
Blood Analysis Report**

26. Did the laboratory discover any difficulties in the receipt of this sample? (1 = yes, 2 = no) ... _____

If no, skip to Item 101.
If yes, continue.

27. Which of the following problems were noted by the central lab?

For the following (1 = yes, 2 = no)

- a. Clerical problems with the data forms accompanying the sample..... _____
- b. Information on the label of the tube incomplete or unsatisfactory..... _____
- c. Sample leakage..... _____
- d. Quantity of sample insufficient..... _____
- e. Incorrect type of sample..... _____
- f. Other (_____)..... _____

101. Date this form completed..... ____ / ____ / ____

102. Certification number of person filling out this form. _____

103. Lab director's signature _____

104. Certification number of lab director..... _____

105. Has form been signed by lab director? (1 = yes, 2 = no)..... _____

106. Date form entered..... ____ / ____ / ____

107. Certification number of data entry person..... _____

Modification of Diet in Renal Disease Study
CENTRAL LABORATORY CAP QUALITY CONTROL

The following form will be used by the Central Biochemistry Laboratory only. It is the complement of Form #21 for the Clinical Centers for the Central Lab.

It will be done every four months and the protocol for receiving the external samples in a somewhat blinded fashion from the GFR Lab is described in the Manual of Operations.

A report of any inconsistent findings will be sent to appropriate study participants.

The two individual values should be recorded for each constituent. Then, the code for the method and instrument used and the mean and standard deviation for that method also must be entered. Finally, the mean and standard deviation for the Comparative Method should be entered.

QUESTION # INSTRUCTIONS

2. Enter the sequential number indicating which CAP sample it is. If the form is completed for a repeat measurement which was originally out of range indicate by entering a 1 in 2b.

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Form # 34
Page 1 of 3

MDRD

Modification of Diet in Renal Disease Study Central Laboratory CAP Quality Control

This form is to be completed by Central Biochemistry Lab personnel every four months from data on CAP samples sent from the GFR Laboratory.

FORM # 34

1. Date specimens received from GFR Lab..... / /
2. a. Sample Number.....
b. Was this a repeat measurement? (1 = yes, 2 = no).....
101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Lab Director's signature
104. Has form been signed by director? (1 = yes, 2 = no).....
105. Date form entered..... / /
106. Certification number of data entry person

2.193

**Modification of Diet in Renal Disease Study
Central Laboratory CAP Quality Control**

RESULTS

Lab Variables	Determination 1 (a)	Determination 2 (b)
3. Date	_ _ / _ _ / _ _	_ _ / _ _ / _ _
Blood		
4. Albumin (g/dl)	_ . _	_ . _
5. Phosphorus (mg/dl)	_ . _	_ . _
6. Creatinine (mg/dl)	_ _ . _	_ _ . _
7. Urea Nitrogen (mg/dl)	_ _ _	_ _ _
8. Uric Acid (mg/dl)	_ _ . _	_ _ . _
9. Bilirubin (mg/dl)	_ _ . _	_ _ . _
10. LDH (IU/l)	_ _ _ _	_ _ _ _
11. SGOT (IU/l)	_ _ _	_ _ _
12. Triglycerides (mg/dl)	_ _ _ _	_ _ _ _
13. Total Cholesterol (mg/dl)	_ _ _ _	_ _ _ _
14. HDL Cholesterol (mg/dl)	_ _ _ _	_ _ _ _
Urine		
15. Creatinine (mg/dl)	_ _ _ . _	_ _ _ . _
16. Urea Nitrogen (mg/dl)	_ _ _ . _	_ _ _ . _
17. Protein (mg/dl)	_ _ _ . _	_ _ _ . _
18. Phosphorus (mg/dl)	_ _ _ . _	_ _ _ . _
19. Sodium (mEq/L)	_ _ _ . _	_ _ _ . _
20. Potassium (mEq/L)	_ _ _ . _	_ _ _ . _

2.194

**Modification of Diet in Renal Disease Study
Central Laboratory CAP Quality Control**

RESULTS

Lab Variables	Method	Mean (PEER)	S.D.	Comparative Method Mean	Comparative Method S.D.
Blood	(c)	(d)	(e)	(f)	(g)
4. Albumin (g/dl)	---	-----	-----	-----	-----
5. Phosphorus (mg/dl)	---	-----	-----	-----	-----
6. Creatinine (mg/dl)	---	-----	-----	-----	-----
7. Urea Nitrogen (mg/dl)	---	-----	-----	-----	-----
8. Uric Acid (mg/dl)	---	-----	-----	-----	-----
9. Bilirubin (mg/dl)	---	-----	-----	-----	-----
10. LDH (IU/l)	---	-----	-----	-----	-----
11. SGOT (IU/l)	---	-----	-----	-----	-----
12. Triglycerides (mg/dl)	---	-----	-----	-----	-----
13. Total Cholesterol (mg/dl)	---	-----	-----	-----	-----
14. HDL Cholesterol (mg/dl)	---	-----	-----	-----	-----
Urine					
15. Creatinine (mg/dl)	---	-----	-----	-----	-----
16. Urea Nitrogen (mg/dl)	---	-----	-----	-----	-----
17. Protein (mg/dl)	---	-----	-----	-----	-----
18. Phosphorus (mg/dl)	---	-----	-----	-----	-----
19. Sodium (mEq/L)	---	-----	-----	-----	-----
20. Potassium (mEq/L)	---	-----	-----	-----	-----

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Modification of Diet in Renal Disease Study
CENTRAL LAB EKG FORM

This form will be completed by the Central EKG Lab personnel. It will be completed for each patient at Baseline 2 and annually at F11, F23, etc...

The form will be completed independently by two readers for each patient. The form will be entered by DCC personnel and a copy of the final report (the form) will be sent to the Clinical Center.

QUESTION #INSTRUCTIONS

- 1.-4. Complete in the usual manner. Copy visit information from Form #18 accompanying EKG tracing.
5. If the EKG tracing is technically satisfactory, enter a 1 and continue to complete the form. Similarly, if it is a borderline tracing, enter a 3 continue. If the tracing is technically unsatisfactory, enter a 2 and skip to item 18. The DCC will report this to the Clinical Center, and the tracing will be repeated at the next monthly visit.
6. Enter the number of beats per minute. Must be averaged with irregular rhythms.
7. If the R wave + S wave is less than 0.6 millivolts in any limb leads, enter a 1. If not, enter a 2.
8. Calculate R wave - Q wave (or S wave if Q<S<R) in millivolts in the AVL lead. Multiply this result by 2 and record the value to the nearest whole number. Record as zero if the R wave and S wave are equal or if the S wave is greater than R. This is the Lewis Index.
9. Sum the S wave in V1 or V2, whichever is greater with the R wave in V5 or V6, which is greater. This is known as the Sokolow Index.
10. Record the height in millimeters of the tallest R wave in leads V5 or V6, whichever is greater.
11. QRS angle. Enter a 1 if angle read is normal ($-15-90^{\circ}$). Otherwise enter a 2 if abnormal.
12. If the rhythm of the heart is sinus, enter a 1. If it is atrial fibrillation, enter a 2. If there is any other type of rhythm, enter a 3 and specify the rhythm.

Modification of Diet in Renal Disease Study
CENTRAL LAB EKG FORM

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|---|
| 13. | Calculate the QT constant by using Bazett's Formula:
$QT \text{ interval (secs)} / \sqrt{R-R \text{ interval (secs)}}$ |
| 14. | a. Record the number best associated with the intraventricular defect read on the EKG.

b. Enter the duration of QRS in seconds. |
| 15. | If there is evidence in the EKG tracing of a prior M.I., enter a
1. Evidence includes the following:
AVF or AVL
Q 0.04 seconds or greater duration
Q 0.03 seconds or greater duration and $Q \geq .25 * R$
Precordial Leads
Absent R in any lead V3 to V6 inclusive
$Q > 0.25 * R$
Q 0.04 seconds or greater duration
If no such evidence is found, enter a 2.
If questionable, enter a 3.
AVF or AVL
Q 0.035 seconds duration but less than 0.04
AND Q less than $0.25 * R$
Precordial Leads
Q 0.035 seconds duration but less than 0.04
Regressive R in lead other than V4 or V6
Q in V1, V2, V3, if R less than 0.30 millivolts |
| 16. | Enter the number best associated with any repolarization indicated on the EKG.

1 = Normal

ST isoelectric or slightly elevated in all leads except AVR
T upright in all leads except diphasic or inverted T acceptable in AVR, V1, V2, and in V3 in women and in those less than 20 years of age; T may also be diphasic or inverted in AVL and in AVF if R is less than 0.6 millivolts.

2 = Non-specific

other than numbers 3 through 9 inclusive.

3 = Suggesting LVH

ST depressed and descending limb of T upwardly convex with T diphasic or inverted in V5 or V6. May be associated with late intrinsicoid deflection. |

**Modification of Diet in Renal Disease Study
CENTRAL LAB EKG FORM**

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|--|
| | 4 = Digitalis Effect
Straight line sagging of ST segments into diphasic or inverted T waves. |
| | 5 = Suggesting Hyperkalemia
Symmetrical upright T waves. |
| | 6 = Suggesting Hypokalemia
Prolonged apparent QTc with V fused into T. |
| | 7 = Hypocalcemia
QTc prolonged due to increased duration of ST. |
| | 8 = Abnormal due to Intraventricular Conduction Defect
ST and/or T changes secondary to intraventricular conduction abnormality. |
| | 9 = Other
Abnormalities including pericarditis, not listed above. Specify. |
| 17. | If any abnormalities other than those touched on in the form are indicated on the EKG, enter a 1 and comment in the space provided. Enter a 2 if there are no other abnormalities indicated. |
| 18. | Enter a 1 if this is the report from Dr. Proudfit. Enter a 2 if by Dr. Underwood. Enter a 3 if it is the consensus. |
| 19. | Enter the date the EKG was read by the physician. |
| 101.-103. | THE ELECTROCARDIOGRAPHER SHOULD THEN SIGN PAGE 3 OF THE FORM, COMPLETE HIS CERTIFICATION NUMBER FOR THE STUDY AND ANSWER YES TO THE NEXT ITEM. THE DCC WILL THEN ENTER THE FORM AND COMPLETE THE LAST TWO ITEMS. |

For DCC Use Only
Rev. 2 12/1/90

E ___
V ___
T ___



**Modification of Diet in Renal Disease Study
Central Laboratory Electrocardiogram Form**

This form is to be completed for baseline at (B2), and annually (starting at F11).

FORM # 35

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of EKG Tracing..... / /
- b. Visit Type.....
- c. Visit Number.....
5. Is the EKG tracing technically satisfactory? (1 = yes, 2 = no, 3 = borderline).....

If the tracing is not satisfactory, skip to Item 18.

Resting EKG

Please review the EKG and answer the following questions:

6. Heart Rate (beats per minute)
7. Is QRS voltage low? (1 = yes, 2 = no)
(< 5 mm all frontal plane leads)
8. Lewis Index (modified)
9. Sokolow Index.....
10. What is the height of the tallest R wave in leads V5 or V6? (mm).....

The EKG technician should forward this form to the EKG reader to complete the remainder of the form.

11. QRS Angle (1 = normal (-15 to 90), 2 = abnormal).....
12. Rhythm.....
 1 = Sinus
 2 = Atrial fibrillation
 3 = Other (20 characters maximum).....
13. QT constant

Modification of Diet in Renal Disease Study Central Laboratory Electrocardiogram Form

QRS

14. a. Conduction defect (intraventricular).....
1 = None
2 = Left anterior hemiblock
3 = Complete left bundle branch block
4 = Incomplete left bundle branch block
5 = Complete right bundle branch block
6 = Complete RBBB with left anterior hemiblock
7 = Complete RBBB with left posterior hemiblock
8 = Incomplete right bundle branch block
9 = Wolff-Parkinson-White syndrome
10 = Intraventricular block (non-specific)
- b. Duration of QRS (secs) (1 = < 0.12, 2 = ≥ 0.12)
15. Does the present EKG indicate evidence of a prior myocardial infarction? (1 = yes, 2 = no, 3 = questionable).....

ST-T

16. Repolarization
a. First Diagnosis.....
b. Second Diagnosis.....
c. Third Diagnosis.....
1 = Normal
2 = Non-specific
3 = Suggesting LVH (left ventricular hypertrophy) in V5 or V6
4 = Suggesting digitalis effect
5 = Suggesting hyperkalemia
6 = Suggesting hypokalemia
7 = Suggesting hypocalcemia
8 = Abnormal due to intraventricular conduction defect
9 = Other abnormality (specify _____)
17. Are there any other abnormalities in the EKG other than those described above? (1 = yes, 2 = no)
- If so, comment (20 characters maximum): _____

18. Which report is this?.....
1 = Reader 1
2 = Reader 2
3 = Consensus reading
19. Date EKG read by physician..... / /
101. Electrocardiographer's signature
102. Certification number of electrocardiographer
103. Has form been signed by electrocardiographer? (1 = yes, 2 = no)
104. Date form entered..... / /
105. Certification number of data entry person

Modification of Diet in Renal Disease Study
AMINO ACID DATA FORM

This is the data which is collected by the central lab personnel and transmitted to the DCC. Patient and visit information should be carefully copied from the mailing form.

2.201

For DCC Use Only
Rev. 4 11/15/90

E ___
V ___
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MDRD

Modification of Diet in Renal Disease Study Amino Acid Data Form

FORM # 36

1. Patient Identification Number.....
2. Patient Name Code:.....
3. Clinical Center
4. a. Date sample drawn..... / /
- b. Visit Type.....
- c. Visit Number.....
- d. Date sample received..... / /
5. Condition of sample at time of receipt.....
 - 1 = Acceptable
 - 2 = Thawed
 - 3 = Spilled
 - 4 = Other (.....)
6. Date sample analyzed..... / /
 - a. Type of analysis/report.....
 - 1 = preliminary (allo/ornithine)
 - 2 = full, complete report

Essential Amino Acids (μ Moles/L)

7. a. Histidine.....
- b. Isoleucine.....
- c. Leucine.....
- d. Lysine.....
- e. Methionine.....
- f. Phenylalanine.....
- g. Threonine.....
- h. 1. Total Tryptophan.....
2. Free Tryptophan.....
3. Bound Tryptophan.....
- i. Valine.....
8. Total Essential.....

Modification of Diet in Renal Disease Study Amino Acid Data Form

Semi-Essential (μ Moles/L)

9. a. Cystine _____
b. Tyrosine..... _____

Nonessential Amino Acids (μ Moles/L)

10. a. Alanine _____
b. Arginine _____
c. Asparagine..... _____
d. Aspartic Acid _____
e. Glutamic Acid..... _____
f. Glutamine..... _____
g. Glycine..... _____
h. Ornithine..... _____
i. Proline _____
j. Serine..... _____
k. Taurine _____
l. Citrulline..... _____
11. Total Nonessential..... _____
12. Total amino acids _____

Other Amino Acids Sometimes Found in Plasma (μ Moles/L)

13. a. Hydroxyproline..... _____
b. α -Aminobutyrate _____
c. Cystathionine..... _____
d. Alloisolucine..... _____
e. 1-Methyl-Histidine..... _____
f. 3-Methyl-Histidine..... _____

101. Date this form completed..... ____/____/____
102. Date form entered..... ____/____/____
103. Certification number of data entry person _____

For DCC Use Only
Rev. 2 10/15/88

E ___
V ___
T ___

Form # 37
Page 1 of 2



**Modification of Diet in Renal Disease Study
Study A and B Randomization Form (Data Coordinating Center)**

This form is to be completed at the Data Coordinating Center when an authorized caller requests a randomization assignment. The Randomization Report should be generated and checks made to be sure the patient is eligible.

FORM # 37

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. Date of Randomization..... / /
5. a. Name of person calling from center:
- b. Certification Number
6. a. Has a copy of the appropriate Informed Consent form been signed by the patient? (1 = yes, 2 = no).....
- b. Date form sent to Data Coordinating Center..... / /
7. What is the patient's average dietary protein intake? (g/kg/day)
8. Final baseline GFR (ml/min/1.73m²)
9. Study Assignment.....
 1 = Study A
 2 = Study B
10. Which blood pressure strata does the patient belong in? (1 = stratum 1, 2 = stratum 2).....

 For Age < 61, Average MAP > 107 = Stratum 1, Average MAP ≤ 107 = Stratum 2.
 For Age ≥ 61, Average MAP > 113 = Stratum 1, Average MAP ≤ 113 = Stratum 2.

 If the patient is in Study B, skip to Item 12.
11. a. What is the estimated slope of inverse creatinine from entrance criteria on Form 3?.....
- b. Is the slope less than -0.0030? (1 = yes, 2 = no)
12. Assignment Number (from randomization schedule)
13. Diet Assigned.....
 1 = Diet K
 2 = Diet L
 3 = Diet M

2.205
PWO 1494

Patient ID Number _____
Rev. 2 10/15/88

Form # 37
Page 2 of 2

**Modification of Diet in Renal Disease Study
Study A and B Randomization Form (Data Coordinating Center)**

- 14. Blood Pressure Group assignment
 - 1 = Moderate MAP Goal
 - 2 = Low MAP Goal

- 101. Date this form completed..... / /
- 102. Certification number of person giving randomization assignment
- 103. Date form entered..... / /
- 104. Certification number of data entry person

2.206
PWO 1494

**Modification of Diet in Renal Disease Study
SAFETY VARIABLE REVIEW FORM**

This form is to be completed by members of the committee when they are reviewing a safety variable.

The original should be mailed to the DCC for key entry. The person taking primary responsibility for completing the form should keep a file copy.

For DCC Use Only
Rev. 5 3/27/90

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**Modification of Diet in Renal Disease Study
Safety Variable Review Form
Clinical Management Committee**

This form is to be completed whenever a designated Clinical Management Committee member reviews a Clinical Management Committee safety variable. The original form should be sent to the DCC for key entry.

FORM # 3 8

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center

For Questions 4 - 6, refer to the Visit Date, Visit Type, and Visit Number when the Safety Variable occurred

- 4. Date of Safety Variable Visit..... / /
- 5. Visit Type.....
- 6. Visit Number.....
- 7. Date of Safety Variable Review

Safety Variables Reviewed (Answer 1 = Yes, 2 = No)

- 8. Weight Loss Protocol Action Item #2.....
- 9. Persistent Symptoms of Low Blood Pressure Action Item #8.....
- 10. Declining Albumin Protocol Action Item #9.....
- 11. Low Albumin Protocol Action Item #10.....
- 12. Declining Transferrin Protocol Action Item #11.....
- 13. High Serum Potassium Action Item #21 if patient is on ACE.....
- 14. Hospitalization (as determined by the committee chairperson)

- 15. Result of review.....
 - 1 = More information is needed for assessment.
 - 2 = Appropriate response not yet implemented.
Committee chair should talk to involved P.I.
 - 3 = Appropriate response has been implemented. No action required.
 - 4 = Refer to external monitoring committee for unblinded review of individual record.

**Modification of Diet in Renal Disease Study
Safety Variable Review Form
Clinical Management Committee**

101. Date this form completed..... _____/_____/_____

102. Certification numbers of committee members who completed this form _____

103. Date form entered..... _____/_____/_____

104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study
PEER GROUP RANGE FORM

This form should be completed for each CAP sample sent to each Center as well as once for each set of CAP samples sent to record the Comparative Methods.

This form is completed by Central Biochemistry Lab personnel upon receipt of the DCC report with CAP data and methods from the Clinical Centers Form #21s.

Upon transmission of this form, the DCC will run the final CAP report.

QUESTION # INSTRUCTIONS

3. Enter the sequential CAP number and whether or not it was a repeat measurement.

[]

For DCC Use Only
Rev. 3 7/15/89

E ___
V ___
T ___

Form # 39
Page 1 of 1



**Modification of Diet in Renal Disease Study
Peer Group Range Form
Clinical Centers**

This form will be completed 16 times by the Central Biochemistry Lab personnel (once for each center and once for the Comparative Method) for each CAP sample sent out.

FORM # 39

- 1. Clinical Center (0 = Comparative Method)
- 2. Date of Analysis at Local Centers / /
(Use date samples sent from CBL for Comparative Method)
- 3. a. Sample Number.....
- b. Was this a repeat measurement? (1 = yes, 2 = no).....

	Peer Group Mean	Peer Group S.D.
4. Serum Urea Nitrogen (mg/dl)	_____	_____
5. Serum Creatinine (mg/dl)	_____	_____
6. Serum Calcium (mg/dl)	_____	_____
7. Serum Magnesium (mg/dl)	_____	_____
101. Date this form completed.....	_____ / _____ / _____	
102. Certification number of person filling out this form	_____	
103. Date form entered.....	_____ / _____ / _____	
104. Certification number of data entry person	_____	

2.208

**Modification of Diet in Renal Disease Study
STOP POINT REVIEW FORM
CLINICAL MANAGEMENT COMMITTEE**

This form should reflect the consensus of the Clinical Management Committee. The diet assignments should not be known. Careful consideration should be given to clearly indicating any and all stop points which have been reached. Each form must be signed.

2.209

For DCC Use Only
Rev. 2 3/28/90

E ___
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**Modification of Diet in Renal Disease Study
Stop Point Review Form
Clinical Management Committee**

This form is to be completed for each stop point reviewed by the committee. It should reflect the consensus of those members reviewing the stop point. The original form should be sent to the DCC for entry into the database.

FORM # 40

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. Study (1 = A, 2 = B, 3 = C).....
5. a. Date stop point declared / /
- b. Date of stop point review / /
6. Which of the following stop points have been reached? (Refer to Section 13 of the Protocol for definitions.) Be sure to indicate each of the stop points reached when multiple ones have occurred concurrently.

For the following: 1 = Yes, 2 = No

- a. GFR (Study A only)
- b. Dialysis.....
- c. Transplantation.....
- d. Low Serum Albumin.....
- e. Weight Loss.....
- f. Very High Serum Phosphorus.....
- g. Serious Medical Conditions.....

Please Comment: _____

7. Which study diet do you believe the patient is on? (1 = Diet K, 2 = Diet L, 3 = Diet M, 4 = Don't know)

**Modification of Diet in Renal Disease Study
Stop Point Review Form
Clinical Management Committee**

101. Date this form completed..... / /
102. Certification numbers of committee members reviewing this stop point. _____

103. Signature of member completing this form: _____
104. Has form been signed? (1 = Yes, 2 = No).....
105. Date form entered..... / /
106. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

**Modification of Diet in Renal Disease Study
DEATH REVIEW FORM
CLINICAL MANAGEMENT COMMITTEE**

This form should reflect the consensus of the Clinical Management Committee. Careful consideration should be given to clearly indicate the cause of death. The form must be signed.

2.2/2

For DCC Use Only
Rev. 1 9/1/88

E ___
V ___
T ___

Form # 41
Page 1 of 1

MDRD

Modification of Diet in Renal Disease Study Death Review Form Clinical Management Committee

This form is to be completed by the Clinical Management Committee to record the consensus of their review of each cause of death. The original form should be sent to the DCC for entry into the database.

FORM # 4 1

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. Date of Death..... / /
5. Cause of Death.....

1 = Cardiovascular Disease	7 = Respiratory Disease
2 = Septicemia	8 = Cerebrovascular Accident
3 = Cancer	9 = Unknown
4 = Trauma	10 = Other (20 characters maximum)
5 = Suicide	(.....)
6 = Renal Disease	

Please Comment: _____

101. Date this form completed..... / /
102. Certification numbers of committee members reviewing death.

103. Signature of member completing form: _____
104. Has form been signed? (1 = yes, 2 = no)
105. Date form entered..... / /
106. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

2.213
PWO 1475

**Modification of Diet in Renal Disease Study
GFR DATA FORM**

This form is a prototype for the data which will be entered by the GFR Laboratory. Some values will be copied from the mailing form, others calculated.

2.214

For DCC Use Only
Rev. 3 10/22/90

E ___
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Form # 42
Page 1 of 2

MDRD

Modification of Diet in Renal Disease Study Determination of Glomerular Filtration Rate

FORM # 4 2

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date samples drawn.....
b. Date samples received.....
5. a. Date of Assay
- b. Visit Type.....
- c. Visit Number.....
- d. Type of GFR done
- 1 = Regularly scheduled GFR 3 = Repeat after GFR action item
 2 = 2 weeks after stop point 4 = Not required by Protocol
- e. Sequence Number.....
6. Sex (1 = M, 2 = F)
7. Body Surface Area.....
8. Elapsed Times for each Period
- a. Elapsed Time 0.....
- b. Elapsed Time 1.....
- c. Elapsed Time 2.....
- d. Elapsed Time 3.....
- e. Elapsed Time 4.....
- f. Elapsed Time 5.....
9. Urine Volumes for each Period
- a. Urine Volume 1.....
- b. Urine Volume 2.....
- c. Urine Volume 3.....
- d. Urine Volume 4.....
- e. Urine Volume 5.....

**Modification of Diet in Renal Disease Study
Determination of Glomerular Filtration Rate**

- 10. Serum Counts for each Period
 - a. Background Serum.....
 - b. Serum Count 0.....
 - c. Serum Count 1.....
 - d. Serum Count 2.....
 - e. Serum Count 3.....
 - f. Serum Count 4.....
 - g. Serum Count 5.....

- 11. Urine Counts for each Period
 - a. Background Urine.....
 - b. Urine Count 1.....
 - c. Urine Count 2.....
 - d. Urine Count 3.....
 - e. Urine Count 4.....
 - f. Urine Count 5.....

- 12. GFR's for each Period
 - a. GFR 1.....
 - b. GFR 2.....
 - c. GFR 3.....
 - d. GFR 4.....
 - e. GFR 5.....

- 13. GFR as one Period.....

- 14. Coefficient of Variation.....

- 15. General Comments (i.e., problems with sample)

- 16. Revision Comments

- 101. Date form created..... / .. / ..

- 102. Certification number of data entry person

Modification of Diet in Renal Disease Study
LOCAL BLOOD PRESSURE FORM

Complete this form at screening and every month throughout the study. Every four months for stop point patients and every year for Study F patients.

If a second blood pressure is done after B3 for eligibility label as B 3.9.

For items 9-11, parts c and d do not need to be completed. Datalex will calculate these values automatically.

This form must also be completed for standing blood pressure measurements at F12, F24, F36, and F48 for both Follow-Up and Study F patients. For standing measures, only the first BP reading needs to be done. All three are not required.

Q4b Visit type. In addition to the usual visit types, type = K was added for Study C post stop point visits.

**Modification of Diet in Renal Disease Study
Local Blood Pressure Form**

First random zero Blood Pressure

9. a. Reading Systolic/Diastolic (mmHg)..... _____/_____
b. Zero value..... _____
(Entry Point 90 will provide)
c. Corrected value (a - b) (mmHg)..... _____/_____
d. MAP _____

Second random zero Blood Pressure

10. a. Reading Systolic/Diastolic (mmHg)..... _____/_____
b. Zero value..... _____
(Entry Point 90 will provide)
c. Corrected value (a - b) (mmHg)..... _____/_____
d. MAP _____

Third random zero Blood Pressure

11. a. Reading Systolic/Diastolic (mmHg)..... _____/_____
b. Zero value..... _____
(Entry Point 90 will provide)
c. Corrected value (a - b) (mmHg)..... _____/_____
d. MAP _____

12. MAP for visit (average 10d, 11d) _____

101. Date this form completed..... ____/____/____

102. Certification number of Blood Pressure measurer _____

103. Date form entered..... ____/____/____

104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

**Modification of Diet in Renal Disease Study
STUDIES F AND G FORM**

This form should be completed every four months for Study F and annually for Study G. Data should be obtained in three possible ways, patient or physician contact or a patient visit.

The form should be completed with as much data as possible leaving not applicable or unknown items blank.

If a visit is held, central blood measurements for creatinine and albumin should be done. Use Form 17 to accompany the samples to the lab. Label Form 17 as visit type and number X4, X8, X12 etc... The X will alert the central lab to know which analyses to do.

If a visit is held and outside information is readily available, complete both sections of the form.

Visit Type and Number must be completed whether contact is made or not. Indicate the type and number it would be if it were held (i.e., X, 4, 8, 12, 16, etc...).

For DCC Use Only
Rev. 4 12/1/90

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Modification of Diet in Renal Disease Study Study F Form

This form is to be completed every six months (± 30 days) from the B0 Visit for Study F patients. Information can be received over the phone or by having a visit. If a visit is held, blood work would be measured centrally using appropriate mailing and result forms. Annually, for Study F patients complete Form 13 as well.

FORM # 4 Z

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of Contact (date of visit, if held)..... / /
(Enter date of final attempt if unsuccessful)
- b. Visit Type..... X
- c. Visit Number.....
- d. Source of Information or type of contacts attempted (1 = yes, 2 = no)
 1. patient.....
 2. other physician or hospital.....
 3. clinic visit.....
 4. other (friend, relative) (.....).....
- e. Reason visit not held or data unavailable within the window.....

1 = All required data received by interview, visit not necessary	8 = Patient refused
2 = Illness	9 = Weather
3 = Hospitalization	10 = Moved
4 = Personal family business	11 = Could not contact
5 = Work related business	12 = Other
6 = Vacation	13 = Unknown
7 = Patient forgot	
5. Status (1 = alive, 2 = dead).....

If dead, Complete Death Notification Form (Form #15)

6. a. Has the patient begun dialysis? (1 = yes, 2 = no).....
- b. Date dialysis began..... / /
- c. Type of dialysis.....

1 = Hemodialysis	4 = CCPD
2 = Home Hemodialysis	5 = IPD
3 = CAPD	9 = Unknown

2221

Modification of Diet in Renal Disease Study Study F Form

7. a. Has the patient had a kidney transplant? (1 = yes, 2 = no)..... _____
b. Date of transplant..... _____/_____/_____
8. Did any hospitalizations occur since the last patient contact? (1 = yes, 2 = no)..... _____
If yes, Complete Unscheduled Attention Form (Form #10) for each hospital stay.
9. How many packs per day does the patient smoke?..... _____
10. Which of the following medications is the patient presently taking? (1 = yes, 2 = no)
a. ACE inhibitors..... _____
b. Calcium Channel Blockers..... _____
c. Beta Blockers..... _____
d. Diuretics..... _____
e. Other antihypertensives..... _____
f. Erythropoietin..... _____
11. Is the patient currently following any special diet therapy? (1 = yes, 2 = no)
a. Very low protein (with supplements)..... _____
b. Low protein..... _____
c. Low salt..... _____
d. Low calorie..... _____
e. Other (_____)..... _____

If information received from sources other than a visit, complete items 12 to 15.

12. a. Reported Actual Body Weight (kg)..... _____
(Be sure to convert pounds to kilograms)
b. Date obtained..... _____/_____/_____
13. a. Reported Blood Pressure (mmHg)..... _____
b. Date of measurement..... _____/_____/_____
14. a. Reported Serum Creatinine (mg/dl)..... _____
b. Date of measurement..... _____/_____/_____

Modification of Diet in Renal Disease
LEISURE TIME PHYSICAL ACTIVITY FORMQUESTION #INSTRUCTIONS

6.-7.

If a patient answers "No" to either of these questions, probe to insure that the patient knows that we are including walking and all other kinds of physical activity and not just organized sports. Watch for a tendency to tell you about walking that is incidental to performing another activity. If, for example, someone says that they walk while doing the housework, this does not (in and of itself) qualify. If, on the other hand, they tell you that they make a point of walking to the grocery (instead of driving) because they want the exercise, you should include it. However, we also ask separately about walking for exercise in item 16, so don't spend too much time here sorting out who walks how much and for what purpose.

If anyone tells you that they are not physically active, explain that "Some people take things for granted that we consider physical activity, so would you mind if I ask a few more questions just to make sure that we don't miss anything...." As in all the questions, you should never show surprise or disapproval at a person's inactivity; instead, strive to make the patient feel that everything they tell you is equally acceptable, so long as it is as accurate as they can make it.

If anyone tells you in item 6 that last week was much less active than most, you may tell them that item 7 asks about other things that they did earlier. Chances are that they will remember last week more accurately than a typical or average week, so discourage a tendency to over-report activities in item 6. Conversely, we want the respondent to include in item 6 things that she spends very little time on.

Each kind of activity should be listed on a separate line. Read the list back to the respondent, coding the activities as you go. Probe for "anything else that you did last week or in the past 12 months?" (While you can postpone entering the code number for each kind of activity until after the interview, make sure that you have enough information to permit you to do so. If, for example, someone says they played tennis, probe whether it was singles or doubles; if they danced, find out what kind of

**Modification of Diet in Renal Disease
LEISURE TIME PHYSICAL ACTIVITY FORM**

Please spell out the nature of the activity if someone gives you a response which appears to fit the "Other" code. While we expect most of the "other" answers to be sufficiently rare to leave them as is, we may want to combine some kinds of activities that are not listed separately with others that are precoded. If we don't know whether "other" refers to baton twirling, to tractor pulling or to something else, we may not classify it properly.

If a participant mentions more activities than can fit on the lines, only include the 6 that they did most frequently.

Once you have a complete list of everything the respondent did last week or last year, turn your attention to the three follow-up questions for each activity. Make sure that the frequencies per year and per week are entered before asking the follow-up question on minutes performing the activity each time. Note that the follow-up questions for activities performed in the past week ask about the frequency and duration of activity in the past year, not just in the past week.

The first follow-up asks for number of weeks per year the patient does the activity. Be sure to include any seasonal variations in this estimate. The second asks about times per week; if someone says that they do calisthenics every morning and every evening except on Sunday when they skip the evening session, the entry should be 13.

Be sure to probe for the number of times an activity is performed in the average week when they do that activity; if someone tells you how many times they did something during certain weeks, probe "And in the average week when you [ACTIVITY], how many times per week did you do that?" Remember that you should only average for the weeks in which the activity was performed at least once.

For each activity listed, ask the respondent, "Each time that you [ACTIVITY], for how many minutes on average do you actually [ACTIVITY]?" Count only time that you are actually doing it." If they say that the amount of time varies, probe for the average time. Record the response. Note: for bowling, each game played counts for about 10 minutes of actual activity.

Activities should be listed under item 6 (done in the last week) or item 7 (done in the past year but not in the past week.) Activities should not be under both.

If you need to complete a "Data Out of Range Form" for any variable in item 6 or 7, the variables are named by letters A

**Modification of Diet in Renal Disease
LEISURE TIME PHYSICAL ACTIVITY FORM**

to F for rows and 1 to 4 for columns; that is, the first "times per week" in item 6 should be labelled F48Q06A3.
If more than 6 activities, ignore others - list only 6.

10.-11. These questions may cause considerable difficulty for patients whose activity patterns vary a lot from day to day. Help these patients arrive a weighted average per day by writing down the hours spent sitting or lying down on each day during a typical week, e.g. 3 days at 5 hours, 2 days at 3 hours, 2 days at 1 hour, and then divide by 7 to calculate the average per day. If the patient can only narrow the answer to a range, then round down to the bottom end of the range.

12. Check for consistency. Item 12 a and b should be at least 7.

13., 14. "Out of house or residence" means anywhere other than inside of the patient's residence, even visiting next door at a neighbor's house. It does not include, however, just going out to the front porch or mail box to pick up the paper, etc.

If anyone wants to know what is meant by: leave your neighborhood", it could be defined as being far enough away that most people would get on a bus or into a car to get there, or far enough away that most people would consider it beyond easy walking distance of where they live.

The answers to those two questions should be checked for consistency.

For DCC Use Only
Rev. 4 10/4/90

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V ___
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Modification of Diet in Renal Disease Study Leisure Time Physical Activity Questionnaire

This form is to be completed with the patient at B1, F10, F22, etc.

FORM # 48

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of visit associated with form..... / /
- b. Visit Type.....
- c. Visit Number.....
5. Date patient completed form..... / /

These few questions ask about physical activity. This includes activities such as dancing and walking for exercise, organized sports such as golf and bowling, and any other activities such as the following.

- | | | |
|------------------|-----------------------|-----------------------|
| 01 = Walking | 12 = Dance Exercise | 23 = Calisthenics |
| 02 = Hiking | 13 = Aerobic Dance | 24 = Softball |
| 03 = Jogging | 14 = Square Dance | 25 = Field Hockey |
| 04 = Running | 15 = Other Dance | 26 = Basketball |
| 05 = Swimming | 16 = Gardening | 27 = Tennis (singles) |
| 06 = Skiing | 17 = Golf (walking) | 28 = Tennis (doubles) |
| 07 = Bicycling | 18 = Golf (with cart) | 29 = Weightlifting |
| 08 = Skating | 19 = Bowling | 30 = Nautilus |
| 09 = Racquetball | 20 = Rowing | 31 = Volleyball |
| 10 = Squash | 21 = Shuffleboard | 32 = Horseback Riding |
| 11 = Badminton | 22 = Canoeing | 33 = Other |

6. Did you participate in any physical activities, recreation or sport in the past week? (1 = yes, 2 = no, 3 = don't know).....

If no or don't know, skip to item 7.

If yes, write down the codes for each of the activities you participated in during the past week and answer the questions about how often "on average" did you do each one in the past 12 months.

Activity	Weeks Per Year	Times per Week	Minutes Per Episode
---	---	---	---
---	---	---	---
---	---	---	---

**Modification of Diet in Renal Disease Study
 Leisure Time Physical Activity Questionnaire**

6. (Continued)

<u>Activity</u>	<u>Weeks Per Year</u>	<u>Times per Week</u>	<u>Minutes Per Episode</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

7. In addition to activities you did last week, are there other physical activities or sports that you participated in during the past 12 months?

<u>Activity</u>	<u>Weeks Per Year</u>	<u>Times per Week</u>	<u>Minutes Per Episode</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

8. About how many hours per week do you usually spend doing heavy household chores such as scrubbing floors, vacuuming, sweeping, yardwork, gardening or snow shoveling?

9. How often do you engage in any regular activity (brisk walking, jogging, bicycling, etc.) long enough to work up a sweat? (1 = not at all, 2 = less than once a week, 3 = at least once a week)

If none or less than once a week, skip to 10.

If at least once a week,

a. How many times per week?

10. During an average 24-hour day, about how many hours do you usually spend sleeping or lying down with your feet up? (Be sure to include time sleeping at night or trying to sleep, resting or stretched out on the sofa watching T.V., etc.)

11. During an average 24-hour day, about how many hours do you usually spend sitting upright? (Be sure to include time sitting at the table eating, driving or riding in a car or bus, sitting watching T.V. or talking.)

12. In the past 12 months have you spent more than seven days in a row in bed most or all of the time? (1 = yes, 2 = no, 3 = don't know)

If no or don't know, skip to item 13.

If yes,

a. In the past 12 months what was the most number of days in a row you spent in bed most or all of the time?

b. How many days in total over the past 12 months did you spend in bed most or all of the time?

**Modification of Diet in Renal Disease Study
Leisure Time Physical Activity Questionnaire**

13. About how often, on the average, do you go out of your house or residence in good weather?.....
1 = Several times a day 4 = About once a week
2 = About once a day 5 = Less than once a week
3 = Several times a week

14. About how often, on the average, do you leave your neighborhood?.....
1 = Several times a day 4 = About once a week
2 = About once a day 5 = 2 or 3 days a month
3 = Several times a week 6 = Less than once a month

15. Think about how often you use stairs on a typical day. Include inside stairs and outside stairs, stairs at home and other places.
a. About how many trips down stairs do you make on a typical day? Count each time you go down a stairway as 1 trip.....
b. About how many flights of stairs do you walk up on a typical day? Please note 10 steps equals 1 flight of stairs.....

16. Do you take walks for exercise? (1 = yes, 2 = no, 3 = don't know)

If no or don't know, skip to Item 17.

If yes,

a. On the average how many city blocks or their equivalent do you walk each day for exercise? Please note 12 city blocks equals 1 mile.
b. In addition to walks for exercise, on the average, how many city blocks or their equivalent do you walk each day as part of your normal routine such as going shopping?.....

Skip to Item 101.

17. On the average, how many city blocks or their equivalent do you walk each day as part of your normal routine, such as when you go out shopping?.....

101. Certification number of person filling out this form

102. Date form entered..... / /

103. Certification number of data entry person

Modification of Diet in Renal Disease Study
RECRUITMENT DATA FOR PATIENTS IN BASELINE

The instructions here are self explanatory except for the new (3/1/90) schedule of completion. This form should be renamed and should be completed at the time of the Screening Visit for all patients screened (not just those in Baseline as the name describes).

The forms should be completed retrospectively for any screened patients - note in item 4 that 9=unknown for patients whom you can't get this backlog of data.

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For DCC Use Only
Rev. 1 6/1/89

E ___
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T ___

Form # 50
Page 1 of 1

MDRD

Modification of Diet in Renal Disease Study Recruitment Data for Patients in Baseline

This form should be completed by June 30, 1989, for all patients enrolled in the study prior to June 15, 1989. Starting with June 15, 1989, this form is to be completed by the recruitment coordinator or study coordinator at each patient's first clinic visit during Baseline.

FORM # 50

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. Where did the person first hear about the study.....
 - 1 = Relative/Friend
 - 2 = Personal Physician
 - 3 = Study Brochure
 - 4 = Newspaper
 - 5 = Radio
 - 6 = TV
 - 7 = Direct Mail
 - 8 = Other (Specify: _____)
 - 9 = Unknown
5. Did this person call the 800 number prior to being in contact with center? (1 = yes, 2 = no) ____
101. Date this form completed..... / /
102. Certification number of person filling out this form.....
103. Date form entered..... / /
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

2.232

**Modification of Diet in Renal Disease Study
OTHER EVIDENCE OF RENAL DISEASE FORM**

This form is to be completed in addition to the form 3 for patients who have a screening visit with a screening creatinine below range, when the Clinical Center wants to notify the DCC that the patient is eligible for a B0 Visit because the patient has other evidence of renal disease.

Question #	Instructions
5.	Enter the serum creatinine that was measured at the Screening Visit (or within a month prior to the Screening Visit) which is below range.
7.a.	Enter the creatinine clearance. This form is only completed for patients who have other evidence of renal disease, which is defined in the Protocol as creatinine clearance less than 70 and at least one of the other criteria listed. If the creatinine clearance is over 70, this form should not be completed. The patient is not eligible and should be noted as such on Form 3.
10.c.	If the urine protein was abnormal, enter a 1. If not, enter a 2.
10.d.	If the WBC or RBC was abnormal, enter a 1. If not, enter a 2.
10.e.	If the hyaline casts, granular casts, red cell casts, or white cell casts were abnormal, enter a 1. If not, enter a 2.
10.f.	If the oval fat bodies were abnormal, enter a 1. If not, enter a 2.
10.g.	If another factor was abnormal, enter a 1. If not, enter a 2.
12.	This form is only completed for patients who have "other objective evidence of renal disease" as defined in the Protocol. If the patient does not have this evidence of renal disease, this form should not be completed. The patient is not eligible and should be noted as such on Form 3.

[]

For DCC Use Only
Rev. 1 8/1/89

E ___
V ___
T ___

Form # 51
Page 1 of 2

MDRD

Modification of Diet in Renal Disease Study Other Evidence of Renal Disease Form

This screening form is to be completed in addition to the Form 3 for all patients who have a screening visit with a serum creatinine below the eligibility range (1.2 to 7.0 for females; 1.4 to 7.0 for males). It will allow the Clinical Center to indicate whether the patient is eligible to enter Baseline on the basis of "other objective evidence of renal disease."

FORM # 5 1

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of Visit.....
- b. Visit Type.....
- c. Visit Number.....
5. Serum Creatinine (mg/dl).....
6. Sex (1 = Male, 2 = Female).....

Creatinine clearance must be <70 ml/min/1.73m² to be eligible.

7. a. Creatinine clearance (ml/min/1.73m²).....
- b. Date of creatinine clearance measurement.....

In addition, the patient must have one of the following criteria to be eligible:

8. a. Abnormal kidney biopsy (1 = yes, 2 = no).....
- b. If yes, date of biopsy.....
9. a. Abnormal kidney size or configuration (1 = yes, 2 = no).....
- b. If yes, date first noted.....
10. a. Abnormal urinalysis (1 = yes, 2 = no).....
- b. If yes, date of most recent abnormal urinalysis.....

Abnormalities noted:

- c. Protein (1 = yes, 2 = no).....
- d. Cells (1 = yes, 2 = no).....
- e. Casts (1 = yes, 2 = no).....
- f. Fat (1 = yes, 2 = no).....
- g. Other (1 = yes, 2 = no) (If other, specify.....)

**Modification of Diet in Renal Disease Study
Other Evidence of Renal Disease Form**

11. History of kidney disease (1 = yes, 2 = no)
12. Does the patient have objective evidence of renal disease? (1 = yes, 2 = no).....
If the response to 8a, 9a, 10a, or 11 is yes, and 7a < 70, then item 12 = yes. If not, then item 12 = no.
101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Date form entered..... / /
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study

DOCUMENTATION OF BLOOD PRESSURE TREATMENT FORM

This form is to be completed at B3, F6, F12, and every six months thereafter for each patient. This form will also be completed at any monthly visit when a patient's blood pressure regimen has changed since the previous visit.

QUESTION #

INSTRUCTIONS

- 4c This form should only be completed at clinic study visits, so the visit number codes should always be whole numbers.
- 5 Complete the form at every visit for which the blood pressure regimen changed. If it changes at the visit, complete the form at the visit. If it changes between two visits, complete the form at the second visit. If the regimen changes more than once between two visits, enter the date of the most clinically important change or, if all of the changes are equally important, enter the date of the most recent change.
- 6 If the form is completed at, for an example, an F3, then the routine F6 form (unless NEW changes have occurred) should indicate a 2.
- 8 Please rank using your study team's best clinical judgement.
If medication side effects are unknown or not applicable, enter 99 for questions a-e then proceed to question 9.
- 10 c-d The answers to these questions are based upon the home blood pressure monitoring logs that each patient should bring with them to the clinic visit and are filled out only if the patient performs home blood pressure monitoring.

For DCC Use Only
Rev. 4 7/23/90

E ___
V ___
T ___

Form # 52
Page 1 of 3

MDRD

Modification of Diet in Renal Disease Study Documentation of Blood Pressure Treatment Form

This form is to be completed at B3, F6, F12, and every six months thereafter for each patient.

This form will also be completed at any monthly visit when a patient's blood pressure regimen has changed since the previous visit.

FORM # 52

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of Visit:..... / .. / ..
b. Visit Type:.....
c. Visit Number:.....
5. Date blood pressure regimen changed..... / .. / ..
If changed more than once, identify first date changed.
If not changed, enter date of visit again.
6. Reason this form is being completed:.....
1 = Change in blood pressure regimen done at or between any MDRD visits, including B3, F6, or F12, etc.
If so, please be sure the medication change is noted appropriately on the Form 5.
If multiple changes occurred, make sure Form 5 reflects current medications.
2 = There is no change in the blood pressure regimen at this time, but this is a B3, F6, or F12, etc. visit.
7. Reason for change(s) in medication(s):.....
1 = Not Effective for BP Control 2 = Possible Side Effects
3 = Probable Side Effects 4 = Not Effective as well as Side Effects
5 = Other (Specify) (20 characters) _____
6 = Not Applicable, no medications were discontinued or reduced or added.
8. If medications were changed due to side effects (2, 3, or 4 above), what possible or probable side effects of medication is the patient experiencing? (See Side Effect Profile Option List on page 2.) (**)
a. Primary side effect noted.....
b. Secondary side effect noted.....
c. Third most important side effect noted.....
d. Fourth most important side effect noted.....
e. Fifth most important side effect noted.....

7 MAP ↓ goal

8 MAP ↓ goal with side eff

** If medication side effects are unknown or not applicable, enter 99 for questions a-e then proceed to question 9.

**Modification of Diet in Renal Disease Study
Documentation of Blood Pressure Treatment Form**

SIDE EFFECT PROFILE OPTION LIST

General:

1. Orthostatic Symptoms
2. Syncope
3. Peripheral Edema
4. Headache
5. Drowsiness/Sedation
6. Fatigue/Tiredness
7. Insomnia
8. Vivid Dreams/Nightmares
9. Sexual Dysfunction
10. Depression
11. Numbness/Tingling of Extremities

Gastrointestinal:

12. Dry Mouth
13. Nausea/Vomiting
14. Anorexia
15. Abdominal Gas
16. Constipation
17. Diarrhea
18. Dysgeusia
19. Liver Dysfunction

Cardiac/Respiratory/Vascular:

20. Cough
21. Dyspnea
22. Wheezing
23. Palpitations
24. Exacerbation of CHF
25. Worsening Claudication
26. Coldness of Extremities

Dermatologic:

27. Rash
28. Pruritus
29. Flushing
30. Alopecia
31. Hypertrichosis
32. Excess Perspiration
33. Angioneurotic Edema

Metabolic/Endocrine:

34. Worsening Glucose Tolerance
35. Worsening Lipid Status
36. Hypokalemia
37. Hyperkalemia
38. Hyperuricemia/Gout
39. Muscle Cramps

Miscellaneous:

40. Anemia
41. Drug-Induced Lupus
42. Pericardial Effusion
43. Gynecomastia

Other:

44. Other Side Effect
45. Bradycardia

None:

99. No Side Effect/Unknown/Not Applicable

9. a. Physician assessment of patient compliance with prescribed blood pressure regimen:.....

- | | |
|---------------------|-----------------------------------|
| 1 = Fully Compliant | 2 = Partially Compliant |
| 3 = Non-Compliant | 4 = Don't Know/No assessment made |

b. Patient assessment of satisfaction with blood pressure regimen and goal:.....

- 1 = Completely Satisfied
- 2 = Troublesome Side Effects or Symptoms of Low BP but Tolerable
- 3 = Intolerable Side Effects or Symptoms of Low BP
- 4 = Other (Specify) _____

**Modification of Diet in Renal Disease Study
Documentation of Blood Pressure Treatment Form**

10. Home Blood Pressure Monitoring
- a. Patient performs home blood pressure monitoring (1 = yes, 2 = no)....._____
- If 2 = no, skip to item 101.
- b. Compared to official study readings, home BP readings are....._____
- 1 = In the same range as clinic readings.
 - 2 = Usually higher than clinic readings.
 - 3 = Usually lower than clinic readings.
 - 9 = Unknown
- c. Does this patient have persistent low BP symptoms (action item levels) based on non-MDRD visit pressures? (1 = yes, 2 = no)
 - d. Does this patient have persistent high blood pressure (action item ranges) based on non-MDRD visit pressures? (1 = yes, 2 = no)
101. Date this form completed..... ____/____/____
102. Certification number of person filling out this form
103. Date form entered..... ____/____/____
104. Certification number of data entry person

FORMS AND ITEMS FOR DIETITIANS
TO BE PARTICULARLY AWARE FROM VOLUME 2

FORM	TITLE	ITEM	DESCRIPTION
—	Instructions	—	Pages 1-11
Packing Slip			To send & order forms from DCC
*Form 3	Screening Visit	19	Height, weight, determination of standard weight
*Form 4	Baseline 0 Visit	38	Height, weight, determination of standard weight
		40	Dietitian time
*Form 5	Monthly Visit	16	Dietitian time
Form 10	Unscheduled Attention	7	Time off diet
Form 11	Stop Point	9	Body weight stoppoint
		14	Diet to be followed
*Form 12	FU After Stop	14	Dietitian time
Form 14	Reasons for Missed Visits	10	Discouraged in diet compliance
		11	Diet not good for health
		14	Combination diet & BP
Form 23	Action Item Response	—	
*Form 24	Data Out-of-Range	—	
*Form 25	Data Change	—	
*Form 47	Study F	11	Diet currently following

*Dietitian is responsible to provide answers to these questions

Modification of Diet in Renal Disease Study

Instructions for completing Form 60

**Food Record/24-Hour Recall Packing Slip
from Clinical Center to NCC**

Purpose: To be used as a cover letter when sending food records/recalls to the NCC.

Clinical Center

Fill in the two-digit code for your clinical center.

Date Sent

Date when the food records/recalls are sent to the NCC.

Certification Number of Person Filling Out Form

Certification Code of the person completing this form. The NCC will contact this person if information or records are missing from the package sent.

Did you attach the Nutrition Cover Sheet (Form 61) to the recalls or records?

Make sure each record/recall has a Nutrition Cover Sheet attached. If all records/recalls do have this form attached, please check yes.

Chart

For each record sent with this mailing fill in the patient ID, name code, the date of Day 1, visit type (B or F), visit number, and form number (Form 63 or Form 64).

Total Records

In the column marked "For Clinical Center use only: Number Sent," record the total number of 24-Hour Recalls and Three-Day Food Record forms sent with this packing slip. The "other" category refers to items that may be sent to the NCC in the future as part of an ancillary study. For an example having the NCC analyze a seven-day food record. This total should not be more than ten (the number of recalls/records listed individually on the packing slip). If more than ten records/recalls are being sent, please use more than one packing slip.

Send the original copy of the packing slip and the records/recalls to the NCC. Be sure to keep a copy of this packing slip in your files.

When the NCC receives the mailing from your center, a data entry staff member will confirm the number of records received, date the records received, indicate who received the mailing, and in which batch the records are placed.

At the end of each month, the NCC will notify each clinic by electronic mail which records were received from that clinic during that month. Please check this listing with your copy of the packing slip. If any records are missing from the NCC list, notify the NCC immediately.

Modification of Diet in Renal Disease
Food Record/24-Hour Recall Packing Slip
from Clinical Center to NCC

Clinical Center: ___ ___ Date Sent: ___ ___/___ ___/___ ___

Certification Number of person filling out form: ___ ___ ___ ___

Did you attach the Nutrition Cover Sheet (Form #61) to the recalls and records? ___ Yes

Line Number	Patient ID	Name Code	Date of Day 1	Visit Type	Visit Number	Form Number
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

TOTAL RECORDS	For Clinical Center use only: Number Sent	For NCC use only: Number Received
24-Hour Recalls		
3-Day Food Records		
Other: _____ (specify)		

Send original of this form to MDRD Study Nutrition Coordinating Center in an envelope with the food records/ 24-hour recalls listed above and retain copy of this form in your Clinical Center file.

For NCC use only: Date received: ___/___/___

By Whom: _____ Batch No. _____

2.234

Modification of Diet in Renal Disease Study

Instructions for Completing Form 61

Nutrition Cover Sheet

Purpose: To supply the NCC with additional information about the completed Food Record Form (24-Hour Recall) or Three-Day Food Record.

This form is to be completed by the dietitian during the completion of either a Food Record Form (24-Hour Recall) (Form 62) or Three-Day Food Record (Form 64).

Patient ID

Fill in the patient's six-digit identification code.

Date of Next Visit

Fill in the date of the patient's next visit.

Name Code

Fill in the patient's four-letter name code.

Clinical Center

Write your Clinical Center two-digit code here.

Visit Type

Either B for Baseline or F for Follow-Up.

Visit Number

Example: 00.5 for B0.A Visit
15.0 for F15 Visit

Form Type

Check whether this sheet is attached to a Food Record Form (24-Hour Recall) or a Three-Day Food Record.

Dietitian's contact with patient

Check whether contact was in person or over the phone.

Dietitian's opinion of information

Check whether the information was reliable or unreliable. If unreliable, check the reason (example: other—the patient could not confirm what he had to eat during the three-day period).

Patient's food intake was:

For each day, check whether the patient's intake was typical of what he/she normally eats or not typical (either more or less eaten than usual or unusual types of food eaten). "Not typical" describes the situation where a person drastically changes the volume of food intake to an extreme for that day. If not typical, check the reason.

a. Holiday (National or Religious)

Examples: a huge Thanksgiving dinner or fasting for religious holiday.

b. Medical/Dental Surgery or Test

Note: This does not include fasting prior to MDRD GFR visits.

c. Illness

Examples: anorexia or nausea.

d. Death in Family

e. Other (specify)

Dietitian's Certification Number

Fill in your five-digit certification number.

Date Documented

The date in which the dietitian who collected the food record or recall completes the documentation of the record/recall.

Reviewer's Certification Number

The food record/recall must be reviewed by a NCC certified documenter other than the documenter who collected the record/recall. This reviewer should fill in his/her certification number.

Date Reviewed

The date in which the reviewer reviews the record/recall and fills in any incomplete information.

Reason for no second documenter:

Document why a second person did not review the food record or recall within a three day period.

Example:

1. Second documenter sick
2. Second documenter on vacation
3. Only one person is certified for dietary documentation

Modification of Diet in Renal Disease Study

NUTRITION COVER SHEET

Attach to the front of the Food Record Form (24-Hour Recall) (Form 62), or Three-Day Food Record (Form 64).

Patient ID: _____

Date of Next Visit: _____

Name Code: _____

Clinical Center: _____

Visit Type: _____

Visit Number: _____

Form Type: Form 62 - Food Record Form (24-Hour Recall)
 Form 64 - Three-Day Food Record

Dietitian's contact with patient: 1) in person
 2) over the phone

Dietitian's opinion of information: 1) reliable
 2) unreliable (please comment)

Patients's food intake was:

Day 1 or 24-hr recall: 1) Typical
 2) not Typical (Check reason why.)
 a) Holiday (National or Religious)
 b) Medical/Dental Surgery or Test
 c) Illness
 d) Death in Family
 e) Other (specify) _____

Day 2: 1) Typical
 2) Not Typical (Check reason why.)
 a) Holiday (National or Religious)
 b) Medical/Dental Surgery or Test
 c) Illness
 d) Death in Family
 e) Other (specify) _____

Day 3: 1) Typical
 2) Not Typical (Check reason why.)
 a) Holiday (National or Religious)
 b) Medical/Dental Surgery or Test
 c) Illness
 d) Death in Family
 e) Other (specify) _____

Dietitian's Certification Number: _____

Date Documented: ____/____/____

Reviewer's Certification Number: _____

Date Reviewed: ____/____/____

Reason for no second documenter: _____

For NCC Use Only

Date Received _____

Date Due _____

Revised 01/09/90

Entry Initials _____

Editing Initials _____

Batch _____

2.235

Modification of Diet in Renal Disease Study

Instructions for completing Form 65

ANTHROPOMETRY FORM

PURPOSE: To record anthropometric measurements.

COMPLETED BY: Dietitian at Baseline 0A and 2, Follow-Up 6 and every four months thereafter.

Following are general guidelines for completing Form 65. Specific questions are not addressed as the form is self-explanatory.

Measurement Guidelines

As a means of quality control and to monitor intra-examiner reliability, all measures are taken and recorded twice. The mean of the two measures is calculated and entered by the Data Coordinating Center (DCC). If the first two measures taken are not within 4.0 mm of each other, two additional measures are taken and all four measures are recorded. The DCC then calculates and records the mean of these measures.

All measurements are collected by the examiner and then repeated before limits are computed. That is, avoid taking two measures in a row at the same body site.

If only one pair of measures must be repeated, wait 30 to 60 seconds between each measure to avoid excessive compression.

Make a note of any unusual conditions of which you feel those analyzing the data should be aware.

Special Codes

60.0 The code 60.0 should be entered when a measure cannot be taken due to "tight skin", the condition in which the patient's skin and subcutaneous adipose tissue cannot be separated from the lean muscle tissue. The code should be entered in the recording space for that skinfold.

70.0 If a skinfold exceeds the measurable limits of the calipers, for example in an obese patient, the code 70.0 should be entered in the recording space for that skinfold.

Quality Control Procedure

Quality control procedures using Form 65 will be initiated in May 1989.

Measures are to be taken by two examiners (dietitians) on one patient each month as a quality control procedure and in order to monitor reliability of measures between examiners.

The DCC will provide a list, determined by random assignment, of three patients on whom measures may be taken. The first patient listed is the preferred one on whom measures should be taken. However, patient #2, then #3 may be used for this procedure should circumstances prevent patient #1 from participating.

Procedure:

1. Data are recorded on Form 65, Pages 1 through 3.
2. Each examiner/dietitian records data on a separate form; that is, a single form is not to be shared.
3. One copy of Form 65 will be labeled with the Patient ID number; the other will be labeled with the center's quality control number.
4. Form 22, the Central Lab QC ID Matching Form, will be completed by the dietitian (this identifies for the DCC the patient whose measures were taken).
5. All measures are taken and recorded twice by each examiner.
6. If the first two measures fall outside the acceptable limits listed below, two additional measures are taken and recorded.

Acceptable Limits

Arm circumference:	Within 0.4 cm
Skinfolds:	Within 4.0 mm
Weight:	Within 0.2 kilograms (200 grams)
Stature:	Within 1.0 cm
Elbow breadth:	Within 0.2 cm (2.0 mm)

If necessary, the code for "tight skin" (60.0) should be entered in the appropriate space for skinfold measurements. If the measure exceeds the limits of the calipers the code 70.0 should be entered in the appropriate space.

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Modification of Diet in Renal Disease Study

ANTHROPOMETRY FORM

There are occasionally large discrepancies between measures (height and/or elbow breadth) at Screening and B0. Specific limits have now been set by the Quality Control Committee. If those limits are exceeded, a third measurement is to be done at the B0A visit. The Form 4 data (that which is discrepant from Form 3) will reject and a query will be written explaining the need for either a correction to incorrectly recorded data or the need for a third measurement. DO NOT RESPOND TO THE QUERY UNTIL THE B0A IS COMPLETE. The third measurement of height and elbow breadth (used to calculate standard weight should be recorded on page 3 (otherwise it is only used for QC purposes) of Form 65 at the B0A visit. These 3rd measures will be the ones which determine the standard weight for the patient. It will overwrite previously collected data. Complete Form 65, answer the query and then the DCC will recalculate and store the correct standard weight. It will appear on future reports for your records (flowsheets, etc.)

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For DCC Use Only
Rev. 4 12/1/90

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Form # 65
Page 1 of 3



Modification of Diet in Renal Disease Study Anthropometry Form

Purpose: To record anthropometric measurements.

To be completed by the dietitian at Baseline 0A and 2, Follow-Up 6 and every four months thereafter. (Note: This form should be entered into Datalex)

FORM # 65

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center
- 4. a. Date of Visit..... / /
- b. Visit Type.....
- c. Visit Number.....

Measurements

Whenever possible, measurements are taken on the right side of the body. Measurements are taken twice and recorded. If the two measures are not within 0.4 cm (4.0 mm) of each other, two additional measurements are taken and all four measures are recorded.

- 5. a. Are arm measurements taken on the right side of the body? (1 = yes, 2 = no)
- If yes, skip to item 6.
- b. If no, code reason.....
 - 1 = Arm casted or injured
 - 2 = Amputation
 - 3 = Other

- 6. Upper arm circumference (cm)
 - a. First measurement.....
 - b. Second measurement.....

Record (c) and (d) only if first 2 measures are not within 0.4 cm.

- c. Third measurement.....
- d. Fourth measurement.....

Modification of Diet in Renal Disease Study Anthropometry Form

Skinfold Measurements:

Code for tight skin = 60.0 "Tight skin" describes the condition in which a patient's skinfold is too tight to pick up to measure (the skin and subcutaneous adipose tissue cannot be separated from the lean muscle tissue). In this situation, the code for tight skin should be entered in the recording space for that skinfold.

Code for skinfold above measurable limits of calipers = 70.0 If a skinfold exceeds the measurable limits of the calipers, the code 70.0 should be entered in the recording space for that skinfold.

7. Triceps (mm)
a. First measurement
b. Second measurement

Record (c) and (d) only if first 2 measures are not within 4.0 mm.

- c. Third measurement.....
d. Fourth measurement

8. Biceps (mm)
a. First measurement
b. Second measurement

Record (c) and (d) only if first 2 measures are not within 4.0 mm.

- c. Third measurement.....
d. Fourth measurement

9. a. Is the subscapular measurement taken on the right side of the body? (1 = yes, 2 = no).....

If yes, skip to item 10.

- b. If no, code reason.....
1 = Area inaccessible due to wound, scarring, etc.
2 = Other

10. Subscapular (mm)
a. First measurement
b. Second measurement

Record (c) and (d) only if first 2 measures are not within 4.0 mm.

- c. Third measurement.....
d. Fourth measurement

Modification of Diet in Renal Disease Study Anthropometry Form

TO BE COMPLETED ONLY WHEN USING THIS FORM FOR QC. WEIGHT MAY BE RECORDED FOR THE B0A VISIT ONLY BELOW IN ITEM 11. WEIGHT AT ALL OTHER VISITS SHOULD BE RECORDED ON FORM 4, 5, 12, OR 47.

ALSO TO BE USED WHEN A THIRD MEASURE OF HEIGHT OR ELBOW WIDTH IS NECESSARY.

11. Weight (kg)
a. First measurement _____ . _____
b. Second measurement _____ . _____
Record (c) and (d) only if first 2 measures are not within 0.2 kilograms.
c. Third measurement _____ . _____
d. Fourth measurement _____ . _____
12. Height (cm)
a. First measurement _____ . _____
b. Second measurement _____ . _____
Record (c) and (d) only if first 2 measures are not within 1.0 cm.
c. Third measurement _____ . _____
d. Fourth measurement _____ . _____
13. Elbow breadth (cm)
a. First measurement _____ . _____
b. Second measurement _____ . _____
Record (c) and (d) only if first 2 measures are not within 0.2 cm.
c. Third measurement _____ . _____
d. Fourth measurement _____ . _____
101. Date this form completed ____/____/____
102. Certification number of dietitian _____
103. Date form entered ____/____/____
104. Certification number of data entry person _____

Modification of Diet in Renal Disease Study

Instructions for Completing Form 63

NCC Phantom Matching Form

At the beginning of the study, the DCC will tell each center what their "phantom" (fake) patient name and ID number will be for the rest of the study.

In the month after the first randomization for each center (and for each subsequent month), the DCC will tell that center what their "original" 3-day food record will be for that month (by ID, name, and visit). This will be a record previously sent to the NCC.

The center dietitian will find his/her file copy of this original, rewrite it in his/her own handwriting (using a different colored pen for the documentation) onto a blank Three-Day Food Record (Form 64) labeled with the ID and name of the phantom patient. The visit code on this phantom record will follow the normal sequence of MDRD three-day food records as listed in the Manual of Operations (the first phantom record visit will be B0 and so on). The date of Day 1 on the phantom record will be the date the dietitian copies the original.

The center dietitian will complete and send to the DCC an NCC Phantom Matching Form (Form 66) for each phantom sent to the NCC.

The NCC will enter the phantom records as if they were originals. The DCC will compare the original records with the matching phantoms to measure the quality of dietary data entry at the NCC.

Example

1. January 1989

The DCC tells Center 15 that their phantom patient name code will be EMSM, ID 123456.

2. February 1989

The DCC tells Center 15 that their original record for February will be name code SEJO, ID 987654, Visit B0 (a record sent to the NCC in January--the date of Day 1 is 1/10/89).

On February 3, the center dietitian finds her file copy of this record, copies it in her handwriting onto a blank food record form, and labels this with name code EMSM, ID 123456, visit B0 (the first in the normal sequence of MDRD visits), dates of Day 1-3: 2/3/89, 2/4/89, 2/5/89.

The center dietitian will complete and send to the DCC an NCC Phantom Matching Form (Form 66) for this phantom record (see completed sample attached).

For DCC Use Only
Rev. 3 1/15/89

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MDRD

Modification of Diet in Renal Disease Study NCC Phantom Matching Form

This form is to be completed monthly when the Clinical Center sends a phantom 3-day food record to the NCC. The phantom food record should contain the complete information from a previous "real" food record, specified by the DCC, copied in the handwriting of the dietitian. The ID and name on the phantom record will be fake, generated by the DCC. The visit code on the phantom record will change from month to month following the normal sequence of visits as specified in the Manual of Operations. (Note: This form should be entered into Datalex)

To be completed by dietitian.

FORM # 66

Original 3-Day Food Record (to be copied)

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. Visit Type
5. Visit Number.....
6. Date of Day 1 of Diet Record.....

Phantom 3-Day Food Record

7. Date of Day 1
8. Visit Type.....
9. Visit Number.....
101. Date this form completed.....
102. Certification number of person completing this form.....
103. Date form entered.....
104. Certification number of data entry person

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Do not send this form to the NCC. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study

Instructions for Completing Form 67

ANTHROPOMETRY MONITORING FORM

PURPOSE: To monitor reliability of measures between examiners.

COMPLETED BY: Measures are taken by two examiners (dietitians) on one patient each month.

Following are instructions for completing Form 67.

Measures are taken on one patient monthly. The choice of patient is random and may be determined by such guidelines as patient consent and convenience of scheduling. It is suggested that the same patient not be used for this exercise more than once, if possible.

All measures are taken once by both examiners. Each examiner should take all the measures once while the other acts as a recorder; they should then switch roles. If the measure taken by one examiner differs from the measure taken by the second examiner by more than the acceptable limits listed below, the measure is repeated by both examiners. Measures that must be repeated at the same body site should be taken at least 30-60 seconds apart. Examiner #1 records the first measure in blank (a) and the repeat measure, if necessary, in blank (b) of each item; examiner #2 records in blanks (c) and (d).

Acceptable limits for differences between measures taken by two examiners are:

<u>Weight:</u>	Within 200 grams
<u>Stature:</u>	Within 1.0 cm
<u>Elbow breadth:</u>	Within 2.0 mm
<u>Arm circumference:</u>	Within 4.0 mm
<u>Skinfolds:</u>	Within 4.0 mm

If necessary, the code for "tight skin" (60.0) should be entered in the appropriate space for skinfold measurements. If the measure exceeds the limits of the calipers, the code 70.0 should be entered in the appropriate space.

For DCC use only
Rev. 11/88

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Modification of Diet in Renal Disease Study

ANTHROPOMETRY MONITORING FORM

PURPOSE: To monitor reliability of measures between examiners.

COMPLETED BY: Two examiners (dietitians) each month.

Form #.....67
1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of Visit.....
b. Visit Type.....F
c. Visit Number.....

Measures

5. Weight (kg).....(Examiner #1) a.
b.
(Examiner #2) c.
d.
6. Stature (cm).....(Examiner #1) a.
b.
(Examiner #2) c.
d.
7. Elbow breadth (cm).....(Examiner #1) a.
b.
(Examiner #2) c.
d.
8. Upper arm circumference (cm).....(Examiner #1) a.
b.
(Examiner #2) c.
d.

2. 243

Patient ID Number _____

Skinfolds: Code for tight skin = 60.0
Code for measure exceeding caliper limits = 70.0

9. Triceps skinfold (mm).....(Examiner #1) a. ___ . ___
b. ___ . ___
(Examiner #2) c. ___ . ___
d. ___ . ___
10. Biceps skinfold (mm).....(Examiner #1) a. ___ . ___
b. ___ . ___
(Examiner #2) c. ___ . ___
d. ___ . ___
11. Subscapular skinfold (mm).....(Examiner #1) a. ___ . ___
b. ___ . ___
(Examiner #2) c. ___ . ___
d. ___ . ___
101. Date this form completed....._ / _ / _
102. Certification number of dietitians completing form:
a) Examiner #1....._ _ _ _
b) Examiner #2....._ _ _ _
103. Date form entered....._ / _ / _
104. Certification number of data entry person....._ _ _ _

Please use MDRD Study mailing labels

WHITE COPY--Send original to MDRD Data Coord. Ctr., Cleveland
PINK COPY --Retain in patient file

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Modification of Diet in Renal Disease Study

Instructions for Completing Form 70

BASELINE DIET PRESCRIPTION FORM

PURPOSE: To provide a calculation and summary of the
Baseline Diet Prescription

COMPLETED BY: Dietitian after Baseline OA and before Baseline
Visit 1. To complete this form you will need:
DCC Flow Sheet and Report of BOA Three-Day Food
Record
(Note: This form should be entered into Datalex).

Following are instructions for completing specific questions on
Form 70.

Page 1Item

5. Usual Daily Dietary Protein Intake** is an average
calculated from the EPI and the Average Dietary Protein
Intake.

- a) EPI (estimated protein intake) gm/kg/day is from the
DCC flow sheet. This is a calculation using urea
nitrogen plus a factor (0.031) for nitrogen loss in
feces and non-urea nitrogen losses times standard body
weight. To convert nitrogen to protein, this is
multiplied by 6.25. U Prot is the 24 hour urine
protein excretion in excess of 5 g/day and is added to
the equation.

$$\text{EPI} = 6.25 \times \frac{\text{Urea Nitrogen} + [0.031 \times \text{Std Bd Wt}]}{\text{Standard Body Weight}} + \text{U Prot}$$

- b) Average Dietary Protein Intake (gm/day) - use the
average of the Three-day food record obtained at
Baseline Visit OA. Code which method was used to
analyze the Three-Day Food Record.

1 = NCC Data Base Nutrient Summary
2 = CDDT (Computerized Diet Design Tool)

- c) Divide Protein Intake in grams per day by Standard Body
Weight to get gram/kg/day.
- d) Total items 5a and 5c
- e) Divide the total in 5c by 2. This gives the average of
the EPI and the dietary protein intake in grams per kg
per day.

**Note calculations should not be completed unless both EPI and
average Dietary Protein Intake Values are available.

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Item6. Baseline Diet Protein Prescription

Use the chart to determine the protein prescription based on the usual protein intake, for example:

A patient with a GFR of 28 and a Usual Protein Intake of 1.1 gm/kg, would have a Baseline Diet Protein Prescription of 0.90 to 1.30 gm/kg/day

or

A patient with a GFR of 18 and a Usual Protein Intake of 0.83 gm/kg/day, would have a Baseline Diet Protein Prescription of 0.60 to 0.90 gm/kg/day.

NOTE: If a patient with a GFR ≥ 25 has a Usual Protein Intake less than 0.90 gm/kg/day, check to determine if protein intake had recently been restricted or if this was a temporary change in eating habits. Determine if the patient and the physician are willing to accept a Baseline Dietary Protein Prescription of 0.90 to 1.30 gm/kg/day. If the patient is not willing to increase his protein intake to 0.90 to 1.30 gm/kg/day, he should be excluded from further participation since it is unlikely he will be a candidate for randomization. (Also see Protocol, Page 9.7)

7. Baseline Diet Calorie Prescription

- a) Code which method was used to analyze Three-Day Food Record from baseline visit OA:

1 = NCC Data Base (Nutrient Summary Report)
2 = CDDT (Computerized Diet Design Tool)

- b) Enter the Average Calorie Intake from BVOA Three-Day Food Record.

- c) Estimated Calorie Range

The recommended calorie range during the Baseline period is 30 to 45 kcals/kg standard body weight per day. However, if a patient has been following a calorie-modified diet (i.e. <30 kcals/kg) before entering Baseline, he/she may continue to follow their current eating plan. Patients desiring to initiate weight reduction at the start of or during the Baseline period should be advised to wait until the Follow-Up period unless extreme circumstances arise. Significant or rapid weight gain or loss (greater than 2 kg) is not recommended during the Baseline Period. Upper calorie ranges may be necessary for patients who are physically very active.

2.246

- d) Baseline Diet Calorie Prescription is a range based on:
- b) the average calorie intake at BVOA
 - c) the estimated calorie range
 - d) clinical judgement

It may be useful to give a wide calorie range during Baseline to enable the patient to have flexibility in his eating choices and then to more closely assess his caloric needs for his Study Diet Prescription.

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For DCC Use Only
Rev. 3 1/15/89

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Form # 70
Page 1 of 2



**Modification of Diet in Renal Disease Study
Baseline Diet Prescription Form**

Purpose: To provide a calculation and summary of the BASELINE DIET PRESCRIPTION.

To be completed by the dietitian after Baseline 0A and before Baseline Visit 1. To complete this form you will need the DCC Flow Sheet and the report of B0A 3-Day Food Record. (Note: This form should be entered into Datalex.)

FORM # Z 0

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of Visit at which this prescription is given..... / /
- b. Visit Type..... B
- c. Visit Number..... 0 1 0

5. Usual Daily Dietary Protein Intake

This is an average calculated by the following:

- a. EPI from DCC flowsheet gm/kg/day (from B0 Visit).....
- b. Method used to determine Average Dietary Protein Intake (gm/kg/day) obtained from the Baseline Visit B0A 3-Day Food Record
 - 1 = NCC Data Base
 - 2 = CDDT

c. Average Protein intake from 3-day food record (gm/kg/day):

$$\begin{array}{rcl}
 \text{Protein Intake from} & \div & \text{Standard Body Weight} \\
 \text{3-day food record} & & \text{(from DCC Flow Sheet)} \\
 \text{(grams per day)} & & \\
 \hline
 & = &
 \end{array}$$

- d. Total items 5a and 5c (gm protein/kg/day).....
 - e. Usual Protein Intake (g/kg/day) Total (from 5d) divided by 2.....
6. Baseline diet protein prescription range (gm/kg/day) Use chart below.
- a. Minimum protein prescription
 - b. Maximum protein prescription

GFR (ml/min/1.73m ²)	Usual Protein Intake (g/kg/day) (item 5e)	Protein Prescription (g/kg/day)
≥25	≥0.90	0.90 - 1.30
	<0.90 ▼	0.90 - 1.30
≤24	0.90 - 1.30	0.90 - 1.30
	≥0.60 - <0.90	0.60 - 0.90
	<0.60	0.60

▼ At end of baseline, would not be eligible to be randomized

**Modification of Diet in Renal Disease Study
Baseline Diet Prescription Form**

7. Baseline Diet Calorie Prescription

a. Method used to determine Average Calorie Intake obtained from Baseline Visit B0A
3-Day Food Record.....
1 = NCC Data Base
2 = CDDT

b. Average Calorie Intake (Kcal/day).....

c. Estimated Calorie Range

i. Minimum:

$$30 \text{ Calories} \times \frac{\text{_____ kg}}{\text{Std Body Weight (DCC Flow Sheet)}} = \text{_____ Kcals}$$

ii. Maximum:

$$45 \text{ Calories} \times \frac{\text{_____ kg}}{\text{Std Body Weight (DCC Flow Sheet)}} = \text{_____ Kcals}$$

d. Calorie Prescription is a range based on clinical judgment, Average Calorie Intake (Question 7b) and Estimated Calorie Range (Question 7c).

i. Minimum Baseline Diet Calorie Prescription (Kcal/day).....

ii. Maximum Baseline Diet Calorie Prescription (Kcal/day).....

101. Date this form completed..... / /

102. Certification number of dietitian completing this form.....

103. Date form entered..... / /

104. Certification number of data entry person.....

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. *Do not send this form to the NCC.* Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study

Instructions for Completing Form 71

STUDY DIET PRESCRIPTION FORM

PURPOSE: To provide a concise summary of the STUDY DIET PRESCRIPTION for calories, ketoacids, supplements, and other special dietary considerations.

COMPLETED BY: Dietitian after Randomization and before Follow-Up Visit 1. (Note: This form should be entered into Datalex)

To complete this form you will need:

- DCC Flow Sheet
- Study Diet Prescription Report from DCC
- Dietary Information Summary Report from DCC

Following are instructions for completing specific questions on Form 71.

Page 1
Item

5. Individualized Calorie Prescription

- a) Review and enter the calorie prescription of the Baseline Diet reported on the Study Diet Prescription Report.
- b) Circle the correct response to the question regarding patient's weight change since the screening visit.
- c) Code and enter (1=Yes, 2=No) if weight loss is currently recommended for management of blood pressure, diabetes or hyperlipidemia.
- d) Circle the correct response to the question regarding the patient's desire to change weight.
- e) Code and enter if Study Diet calorie goals are recommended for:
1 = weight loss 2 = weight gain 3 = maintenance

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- f) Total Calorie Prescription should not be less than 30 kcal/kg/SBW/day unless weight loss is recommended for management of blood pressure, diabetes or hyperlipidemia, or if the patient desires to lose weight and the dietitian also recommends weight loss. The calories prescribed should not be less than 25 kcal/kg/day. If the lower end of the recommended calorie range is less than 25 kcal/kg, state the rationale. (Use a maximum of 20 characters to enter reason for low calorie prescription.)

Calories may be prescribed up to 45 calories/kg/day for patients who are physically very active. If calories are recommended above 45/kg/day, enter the rationale.

Page 2

Item

6. Standard Prescription for Vitamin Mineral Supplement

- a) MDRD Multi-Vitamin Tablet - enter the number of tablets prescribed per day (all study patients are prescribed 1 tablet per day.)
- b) Iron Supplement - enter the iron supplement prescribed in mg of elemental iron per day (study K and L patients should receive at least 60 mg per day). If no iron supplement is prescribed, enter zero.
- c) Code and enter type of iron supplement:
- 1 = ferrous sulfate
 - 2 = ferrous fumarate

7. Calcium Supplement Prescription

- a) The recommended MDRD calcium intake is between 1450 and 1550 mg per day. Use clinical judgement or 1500 mg as a recommended intake.
- b) Calculate and enter the estimated amount of dietary calcium prescribed based on a CDDT analysis of the 7-day menu. If the 7-day menu is not available, estimate the dietary calcium prescribed by the number of servings of dairy products included in the menu plan.
- c) Subtract the estimated dietary calcium intake of the 7-day menu (7b) from the recommended calcium intake (7a) and enter the calcium prescription in mg.

- d) Enter the name of the Calcium Supplement prescribed and code as listed below:

<u>Name</u>	<u>Dosage of Elemental Calcium</u>
1 = BIO CAL - 250	250 mg
////2/7/BIO/CAL/+/500//////////500/mg	500 mg deleted 7-10-89
3 = CALIRATE	600 mg
4 = CAL SUP	300 mg
5 = OS CAL (also chewables)	500 mg
6 = TUMS - REGULAR	200 mg
7 = TUMS - EXTRA STRENGTH	300 mg
8 = ROXANE (GENERIC)	500 mg
9 = Calcium Citrate	200 mg
10 = Tums Liquid	400 mg per teaspoon
11 = OsCal	250 mg
12 = Calcium glubionate (liquid)	115 mg per teaspoon
13 = Calcium citrate (effervescent)	500 mg
14 = Roloids	130 mg
15 = Phos-Ex	250 mg
16 = Phos-Ex	125 mg
17 = Phos-Ex	167 mg
18 = Phos-Ex	62 mg

- e) Enter the dosage of elemental calcium per tablet (mg)
- f) Divide the Calcium Prescription (7c) by the dosage per tablet (7e) to determine the number of calcium tablets prescribed per day. If the result is not a whole number, usual rounding rules may not apply. You may need to round up or down to best meet the prescription; either method is satisfactory.
8. Ketoacid Tablets Prescription - only for Diet K patients who are prescribed tablets. For all others, enter zero.
- a) Enter the number of Ketoacid tablets prescribed per day. (See the Study Diet Prescription Report. Daily dose = 0.28 mg per kg standard body weight. One tablet contains 0.93 gm ketoacids.)
- b) Divide the number of Ketoacid tablets between the meals eaten based roughly on the calorie distribution of the meals. For example, if a patient's usual calorie intake at breakfast is approximately 1/4 of total calories for the day, then allocate the number of ketoacid tablets in a similar distribution. If a patient skips a meal, he would divide the tablets between the remaining meals.
9. Ketoacid Packets Prescription - only for Diet K patients who are prescribed packets. For all others enter zeros.
- a) Enter the total number of Ketoacid packets prescribed per day (See the Study Diet Prescription Report. Daily dose = one packet [2.8 gm] per 10 kg Standard Body Weight.)

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- b) Divide the number of Ketoacid packets between the meals eaten based roughly on the calorie distribution of the meals. For example, if a patient's usual calorie intake at breakfast is approximately 1/4 of his total calories for the day, then divide the number of ketoacid packets in a similar distribution. If a patient skips a meal, he would divide the packets between the remaining meals.

10. Other Dietary Consideration

- a) Sodium - The decision to limit sodium intake should be discussed with the physician. Then enter the code which best describes the adjustment necessary. (1-4)

- 1 = blood pressure management
- 2 = other reason or condition
- 3 = both of the above
- 4 = no reduction of sodium is necessary

Note: If a patient enters the study already following a sodium restricted eating pattern, yet the physician does not feel that this reduction is necessary, the answer to 10(a) should be "4". The decision should be made at the clinical center as to whether the patient may stay at that level of intake or be counseled to increase sodium.

If the patient is already following a sodium restricted eating pattern and the physician feels that no further adjustment is necessary, enter "4" in item 10(a).

However, if the patient enters following a sodium restricted eating pattern and the physician prescribes one that is lower, the answer to 10(a) should be "1", "2", or "3".

- b) If reduction is recommended for blood pressure management calculate the reduction using an average of the urine sodium values (mEq) from the 24-hour urine collections from Baseline Visits 0, 1, 2, and 3 (See Study Diet Rx Report). To convert mEq to mg multiply by 23. A reduction of 30% of the average urine sodium excretion is recommended for management of blood pressure. Multiply urine sodium excretion in mg by 0.70 to obtain a 30% reduction; enter the sodium prescription in 10d. The percent reduction of 30% is a recommendation which should be evaluated on a patient to patient basis. An adjustment other than 30% may be used if clinically appropriate. For example, if a patient has already reduced his sodium intake a 20% reduction might be recommended. In this case follow this example by crossing out the .70 and use the .80% reduction:

$\frac{\text{Average Urine Sodium Excretion from Visits 0,1,2, and 3 (See Study Diet Rx Report)}}{\text{mEq}} \times 23 \times \text{Atomic Weight}$

~~$0.70 = \frac{\text{---}}{\text{---}}$

This constitutes a reduction of 30%~~

$0.80 =$

This constitutes a reduction of 20%

There is no data entry range check on the calculation for milligrams of sodium per day.

- c) If sodium reduction is necessary for a condition other than blood pressure and/or if amount is adjusted by physician, enter the condition or note MDRX (use a maximum of 20 characters). This is a good place to enter the exact percent used in 10.b. In this way this information becomes part of the data base. For example: (Comment: 20% reduction used)
(20 characters maximum)
- d) Enter Sodium Prescription in mg. The Sodium prescription should be the number obtained in 10b. Dietary sodium should not be less than 1200 mg.

11. Alcohol Intake

- a) Code and enter if reduction is necessary for:
 - 1 = blood pressure
 - 2 = other reasons or conditions
 - 3 = both
 - 4 = no reduction is necessary
- b) If alcohol reduction is necessary for a condition other than blood pressure, enter the condition. (Use a maximum of 20 characters)
- c) Enter the number of alcohol equivalents per day:
 - 1 alcohol equivalent =
 - 1 1/2 oz 80 proof distilled spirits (whiskey, gin, vodka, etc.)
 - 4 oz dinner wine
 - 12 oz beer

Limit intake to 2 or fewer alcohol equivalents per day or as recommended after consulting the physician. This recommendation is to be evaluated on a patient to patient basis. There is no data entry range to check on the number of drink equivalents that you determined.

12. Potassium Prescription

- a) Code and enter (1 = yes, 2 = No) if a special prescription is necessary for dietary potassium intake. The recommended intake is 50 - 150 mEq or 1050 - 5850 mg per day
- b) Enter Potassium Prescription in mg. (If no special prescription, leave blank.)

13. Phosphorus Prescription

- a) Code and enter (1 = yes, 2 = no) if a special prescription is necessary for dietary phosphorus. This is determined by the serum value. If the value is out of range (<2.5 or >4.5 mg/dl), the prescription should be determined by the physician.
- b) Enter Phosphorus Prescription in mg. (If no special prescription, leave blank.)

14. Percent of Calories from nutrients - Code and enter (1 = yes, 2 = No) if percent of calories needs to be adjusted for:

- a) diabetes
- b) hyperlipidemia
- c) other (specify) using a maximum of 20 characters.

If yes:

- d) Enter percent of calories from fat. Recommended distribution is less than 45%.
- e) Enter percent of calories from carbohydrate. Recommended distribution is 45 to 60 percent.



**Modification of Diet in Renal Disease Study
Study Diet Prescription Form**

Purpose: To provide a concise summary of the STUDY DIET PRESCRIPTION for calories, keto acids, supplements, and other special dietary considerations.

To be completed by the dietitian after Randomization and before Follow-Up Visit 1. (Note: This form should be entered into Datalex)

To complete this form you will need the DCC Flow Sheet and the Study Diet Prescription Report.

FORM # Z 1

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of visit at which this prescription is given..... / /
- b. Visit Type E
- c. Visit Number.....
5. Individualized Calorie Prescription
 - a. Review Baseline Diet Calorie Prescription (See Study Diet Rx Report)
 - i. Minimum Baseline Diet Calorie Prescription
 - ii. Maximum Baseline Diet Calorie Prescription.....
 - b. Has patient's weight changed since Screening Visit?
 - 1 = Lost
 - 2 = Gained
 - 3 = No Weight Change
 - c. Is weight loss recommended for management of: (1 = yes, 2 = no)
 - i. Blood Pressure
 - ii. Diabetes
 - iii. Hyperlipidemia.....
 - d. Does patient desire to change weight?.....
 - 1 = Lose
 - 2 = Gain
 - 3 = Does not want to change

**Modification of Diet in Renal Disease Study
Study Diet Prescription Form**

5. (Continued)

- e. Study calorie goals are recommended for: (Code 1, 2, or 3).....
1 = Weight loss
2 = Weight Gain
3 = Maintenance
- f. Total Calorie Prescription (Kcal/day) Adjust calorie range as necessary based on the above considerations and clinical judgment
- i. Minimum Total Calorie Prescription.....
- ii. Maximum Total Calorie Prescription.....
- iii. If calorie range is less than 30 or greater than 45 calories/kg, note rationale:

(20 characters maximum)

6. Standard Prescription for Vitamin Mineral Supplements

- a. MDRD Multi-Vitamin Tablets (tablets/day) (All study participants should be prescribed 1 tablet per day.).....
- b. Iron Supplement (mg/day) (Study Diet L and K: at least 60 mg/day elemental iron). Enter "0" if not prescribed.
- c. Source of Iron:.....
1 = Ferrous Sulfate
2 = Ferrous Fumarate

7. Calcium Supplement Prescription

- a. Recommended MDRD Calcium Intake (must be between 1450 mg and 1550 mg per day) is based on clinical judgment (mg/day).....
- b. Estimated calcium intake (mg/day) is based on analysis of 7-day menu plan or prescribed number of servings of dairy products.....
- c. Calcium Prescription (mg/day) (Subtract 7b from 7a)
- d. Calcium Supplement Code Number.....
- Name of Calcium Supplement _____
(name)
- e. Dosage of elemental calcium per tablet (mg)
- f. Number of Calcium Tablets calculated by: (If decimal obtained, round up to the nearest whole number.)

$$\begin{array}{ccccccc} \text{-----} & & \div & & \text{-----} & & = & & \text{-----} \\ \text{Ca}^{++} & & \text{divided} & & \text{dosage/tablet} & & & & \\ \text{Supplement} & & \text{by} & & \text{(7e)} & & & & \\ \text{Prescription} & & & & & & & & \\ \text{(7c)} & & & & & & & & \end{array}$$

Modification of Diet in Renal Disease Study Study Diet Prescription Form

8. **Keto Acid Tablets Prescription**--For participants on Diet K who are on prescribed tablets. (Daily dose = 0.28 gm per kg Standard Body Weight. One tablet contains 0.93 gm keto acids.) If not prescribed, enter "0".

a. Total Number of Keto Acid Tablets Prescribed Daily
(See Study Diet Prescription Report)

Distribute tablets based roughly on calorie distribution of meals:

b. Number of tablets at morning meal

c. Number of tablets at midday meal

d. Number of tablets at evening meal

9. **Keto Acid Packets Prescription**--For participants on Diet K who are on prescribed packets. (Daily dose = one packet (2.8 gm) per 10 kg Standard Body Weight.) If not prescribed, enter "0".

a. Total Number of Keto Acid Packets Prescribed Daily
(See Study Diet Prescription Report)

Distribute packets based roughly on calorie distribution of meals:

b. Number of packets at morning meal

c. Number of packets at midday meal

d. Number of packets at evening meal

OTHER DIETARY CONSIDERATIONS

10. **Sodium**

a. Is reduction necessary for blood pressure management or other medical conditions?

1 = BP

2 = Other

3 = Both

4 = No reduction necessary

If no reduction necessary, skip to item 11.

b. Recommended reduction for blood pressure management calculated by:

$$\begin{array}{ccccccc} \text{_____ mEq} & \times & 23 & \times & 0.70 & = & \text{_____} \\ \text{Average Urine Sodium} & & \text{Atomic} & & \text{This constitutes} & & \\ \text{Excretion from Baseline} & & \text{Weight} & & \text{a reduction} & & \\ \text{Visits 0, 1, 2 and 3} & & & & \text{of 30\%} & & \\ \text{(See Study Diet Rx Report)} & & & & & & \end{array}$$

AND / OR

c. Other adjustment (Comment: _____)
(20 characters maximum)

d. Sodium prescription (mg/day)*

* Sodium prescription should not be below 1200 mg per day.

**Modification of Diet in Renal Disease Study
Study Diet Prescription Form**

11. Alcohol Intake

a. Is reduction necessary for blood pressure management or other conditions?....._____

- 1 = BP
- 2 = Other
- 3 = Both
- 4 = No reduction necessary

If no reduction necessary, skip to item 12.

b. Other adjustment (Comment: _____)
(20 characters maximum)

If yes, limit intake to 2 or fewer alcohol equivalents per day (see Instructions for Form #71)
or as recommended by physician.

c. Number of Alcohol Equivalents/day_____

12. Potassium Prescription (mg/day) by physician.

a. Is a special potassium prescription necessary? (1 = yes, 2 = no)....._____

If no, skip to item 13.

b. Potassium Prescription by physician (mg/day)....._____

13. Phosphorus Prescription (mg/day) by physician.

a. Is a special phosphorus prescription necessary? (1 = yes, 2 = no)....._____

If no, skip to item 14.

b. Phosphorus Prescription by physician for serum values out of range
(mg/day)....._____

14. Does Percentage of Calories from nutrients need to be adjusted for: (1 = yes, 2 = no)

a. Diabetes_____

b. Hyperlipidemia....._____

c. Other (specify): _____
(20 characters maximum)

If yes:

d. Percent of calories from fat (Recommended = <45%)_____

e. Percent of calories from carbohydrate (Recommended = 45% to 60%)....._____

**Modification of Diet in Renal Disease Study
Study Diet Prescription Form**

- 101. Date this form completed....._ _ / _ _ / _ _
- 102. Certification number of dietitian completing form....._ _ _ _ _
- 103. Date form entered....._ _ / _ _ / _ _
- 104. Certification number of data entry person_ _ _ _ _

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. *Do not send this form to the NCC.* Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study

Instructions for Completing Form 72

SPECIAL DIETARY CONSIDERATIONS FORM

PURPOSE: To provide a calculation and summary of any changes to the Study Diet or additional Dietary Supplements or Prescriptions.

COMPLETED BY: Dietitian ONLY for patients who require changes in diet prescription due to Action Items or additional dietary considerations at any time during Follow-Up.

(Note: This form should be entered into Datalex)

To complete this form you will need:

DCC Flow Sheet

Nutrient Summary Report from NCC

Dietary Information Summary Report

INSTRUCTIONS:

For Study C patients - Post stop point use visit type = K. Only visit numbers with .0 or 1.5 and 2.5 are allowed. No .8 or .9's are acceptable.

Item 8: Alteration in Energy and Protein Prescription for Albumin and Transferrin Action Items and for Patients on Diet K not Taking Ketoacids and Whose Unadjusted EPI is <0.40 g/kg/day.

A) Energy

For patients with an Action Item for declining or low serum albumin or transferrin, the following steps should be taken (see Protocol, Section 13):

1. Repeat the measurement in one month.
2. If it persists, alter energy prescription as indicated below:

DIET	WEIGHT (%SBW)	ACTION
All	≤ 120% (≤ 115% in diabetics)	Increase energy intake (until patient objects)
All	> 120% (> 115% in diabetics)	Increase energy intake (until patient objects or gains weight)*

*Interpretation: The goal is to provide sufficient calories to resolve the Action Item but not to the degree that the patient gains excessive weight.

The measurement should be evaluated again after one month of increased caloric intake. Whether further action should be instituted at this time, such as increasing protein intake, depends on evaluation of change in the measurement (if any) and clinical judgement.

For example, if serum albumin or transferrin has not declined further, or has slightly increased (yet not to normal), the goal would be to continue increasing the caloric intake without instituting an increase in the protein prescription.

If, however, after one month a patient were unable to increase caloric intake sufficiently enough to maintain or increase the albumin or transferrin, and it is your assessment that this will not change, an increase in protein intake would be warranted (see below).

If after two to three months of increased caloric intake the measure does not begin to increase, or increases at such a marginal rate that the patient is at potential risk, an alteration in the protein intake should be made.

(Changes in calorie prescription must be noted on Form 72, Item 10.)

B) Protein

3. For patients on Diet K who are not taking keto acid supplements and whose unadjusted EPI < 0.4 g/kg/day and where the Compliance Committee, in consultation with the P.I., recommends increasing the protein prescription, the prescription should be changed to 0.575 g/kg/day.
4. For albumin and transferrin action items, refer to Table 13.1, Section 13 of the Protocol for alterations in the protein prescription. Examples for each diet follow.

Diet M - Most recent EPI (UNA) 1.0 g/kg/day:

1. Do not alter protein prescription or intake. Continue to monitor serum albumin or transferrin level. Continue to encourage adequate calorie intake.

Diet M - Most recent EPI (UNA) < 1.0 g/kg/day:

1. Increase protein intake to 1.0 g/kg/day. (Note that the prescription is 1.3 g/kg/day. However, this is an example where - despite the prescription - the patient is ingesting less than 1.0 g/kg/day. Thus, the prescription does not change.)

2. The added protein should be of high biological value (HBV). For example, if the patient is ingesting 0.8 g/kg/day (defined by EPI/UNA), 0.2 g/kg/day (1.0 - 0.8) should be HBV. Make note of any action taken on the Action Item Response Form (Form 23) and on the Summary of Counseling Plan (Form 76).

Diet L - Most recent EPI (UNA) 0.7 g/kg/day:

1. Do not alter protein prescription or intake. Continue to monitor serum albumin or transferrin level. Continue to encourage adequate calorie intake.

Diet L - Most recent EPI (UNA) 0.55 - 0.69 g/kg/day:

1. Increase protein prescription to 0.7 g/kg/day.
2. Complete Special Dietary Considerations Form (72).
3. Note that half of the protein that is added must be HBV. To calculate the new prescription, follow these steps:

Example: Patient ingesting 0.55 g/kg/day,
SBW = 60.0 kg

a.
$$\begin{array}{rcll} 0.70 & \times & 60.0 & = & \underline{042.0} \\ \text{New Protein Rx} & & \text{SBW} & & \text{gms protein} \end{array}$$

- b. See Study Diet Rx Report, item 5, for portion of former Total Protein Rx that must be HBV: $\underline{12.1}^*$ gms/day

* (Former rx of 34.5gms protein/day x 0.35 = 12.1 for this example)

- c. Take the difference between the current intake (0.55 g/kg) and the new prescription (0.70 g/kg); divide by 2:

$$(0.70 - 0.55)/2 = 0.075 \text{ g/kg/day}$$

(This provides half of the added protein as HBV.)

- d. Multiply (c) by the SBW to obtain gms protein/day: $0.075 \times 60.0 = 4.5 \text{ gms}$

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- e. Add (b) and (d) to obtain the portion of the new protein prescription that must be high biological value: $12.1 + 4.5 = 16.6$

New Protein Prescription = 42.0 gms/day
(0.70 g/kg)
Amount which must be HBV = 16.6 gms/day

Diet L: - Most recent EPI (UNA) < 0.55 g/kg/day:

- Increase protein intake to 0.55 gm/kg/day:

$$\frac{0.55 \times \text{SBW}}{\text{New Protein Intake}} = \frac{\text{gms protein/day}}{\text{gms protein/day}}$$
- Calculate portion of new intake which must be HBV Protein:

$$\text{Gms Protein/Day} \times 0.35 = \text{_____} . \text{_____}$$
- Note that the actual prescription does not change (stays at 0.575 g/kg/day). Dietary intake, however, is increased to 0.55 g/kg/day. Record action taken on the Action Item Response Form (23) and in the Summary of Counseling Plan (Form 76). Note: Form 72 does not need to be initiated as the prescription did not change.

Diet K - Most recent EPI (UNA) 0.40 * g/kg/day:

- Do not alter protein prescription or intake. Continue to monitor serum albumin or transferrin levels. Encourage adequate calorie intake.

*DCC calculates EPI(UNA) values for Diet K based on dietary intake only; the contribution from the ketoacid supplement is not included.

Diet K - Most recent EPI (UNA) 0.28 - 0.39 g/kg/day:

- Increase protein prescription to 0.4g/kg/day.
- Complete Special Dietary Considerations Form (Form 72).

Diet K - Most recent EPI (UNA) < 0.28 g/kg/day:

- Increase protein intake to 0.28 g/kg/day.

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2. Note that the actual prescription does not change (stays at 0.28 g/kg/day). The remedial action is to increase intake to 0.28 g/kg/day. This should be noted on the Action Item Response Form (23) and on the Summary of Counseling Plan (Form 76).

Item 9: Altered Phosphorus Prescription

- a) Enter either 1=Yes or 2=No. If "2" is entered, 9b and 9c may be left blank.
- b) Refer to Table 13.2, Section 13 of the Protocol for alterations in the phosphorus prescription. Examples for each diet follow.

TREATMENT OF HIGH SERUM PHOSPHORUS**Diet M**

Phosphorus intake (from most recent Three-Day Food Record as analyzed by the NCC)

> 20 mg/kg/day:

1. Reduce intake to 16-20 mg/kg/day
2. Prescription does not change.
3. Note action taken on the Action Item Response Form (23) and Summary of Counseling Plan (Form 76).
4. Continue to monitor phosphorus intake and serum phosphorus levels.

Phosphorus intake 16-20 mg/kg/day:

1. Reduce phosphorus intake to less than 16 mg/kg/day (new goal depends on serum level, patient's ability to reduce intake, physician's recommendation).
2. Do not reduce protein intake to less than 1 g/kg/day.
3. Complete Special Dietary Considerations Form (72) to record new prescription.

Phosphorus intake <16 mg/kg/day:

1. Add phosphorus binders (physician prescription).
2. Reduce phosphorus prescription to <16 mg/kg/day; complete Form 72.
3. Monitor phosphorus intake with the goal of maintaining intake at < 16mg/kg/day without reducing protein intake to less than 1 g/kg/day. (Primary treatment is addition of binders).

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Diet L

Phosphorus intake > 10 mg/kg/day:

1. Reduce intake to 5-10 mg/kg/day.
2. Prescription does not change.
3. Note action taken on the Action Item Response Form (23) and Summary of Counseling Plan (Form 76).

Phosphorus intake ≤ 10 mg/kg/day:

1. Add phosphorus binders (physician prescription).
2. Prescription does not change. Maintain intake at 5-10 mg/kg/day.
3. Complete Special Dietary Considerations Form.

Diet K

Phosphorus intake > 9 mg/kg/day:

1. Reduce phosphorus intake to 4-9 mg/kg/day.
2. Prescription does not change.
3. Note action taken on the Action Item Response Form (23) and Summary of Counseling Plan (Form 76).

Phosphorus intake ≤ 9 mg/kg/day:

1. Add phosphorus binders (physician prescription).
2. Prescription does not change. Maintain intake at 4-9 mg/kg/day.
3. Complete Special Dietary Considerations Form (Form 72).

Item 10: Altered Calorie Prescription

- a) Enter either 1=Yes or 2=No. If "2" is entered, 10b and 10c may be left blank.
- b) Refer to the most recent Dietary Information Summary Report and enter the current calorie prescription in kcal/day.
- c) Enter the number code describing the reason for the calorie adjustment in the blank. If "other" is selected, up to 20 characters may be used (including letters and spaces) to note the reason.
- d) Record the altered prescription in kcal/day.

Item 11: Altered Calcium Supplement Prescription

- a) Enter either 1=Yes or 2=No. If "2" is entered, skip to next item. Otherwise, indicate reasons for change by answering each of the next three questions.
- b) The recommended intake may be less than 1300 mg or greater than 1700 mg based on the clinical judgement of the physician.
- c) Enter the estimated calcium intake in mg/day using the most recent NCC analysis value.
- d) Record the altered prescription by:
 - 1. Subtracting 11c from 11b or
 - 2. By entering another adjustment.
- e) Enter the name of the calcium supplement and code as listed below:

<u>Name</u>	<u>Dosage of Elemental Calcium</u>
1 = BIO CAL 250	250 mg
2 = BIO CAL 500	500 mg del 7-10-89
3 = CALTRATE	600 mg
4 = CAL SUP	300 mg
5 = OS CAL (also chewables)	500 mg
6 = TUMS - REGULAR	200 mg
7 = TUMS - EXTRA STRENGTH	300 mg
8 = ROXANE (GENERIC)	500 mg
9 = Calcium Citrate	200 mg
10 = Tums Liquid	400 mg per tsp.
11 = OsCal	250 mg
12 = Calcium glubionate (liquid)	115 mg
13 = Calcium citrate (effervescent)	500 mg
14 = Roloids	130 mg
15 = Phos-Ex	250 mg
16 = Phos-Ex	125 mg
17 = Phos-Ex	167 mg
18 = Phos-Ex	62 mg

- f) Enter the dosage of elemental calcium per tablet (mg).
- g) Divide the calcium supplement prescription (11d) by the dosage per tablet (11f) to determine the altered number of calcium tablets prescribed per day. if the result is not a whole number, usual rounding rules may not apply. You may need to round up or round down to best meet the prescription; either method is satisfactory.
- h) Enter the amount of calcitriol (ug/day) prescribed (for patients with a persistent adjusted serum calcium < 8.5 mg/dl and phosphorus < 4.5 mg/dl). See Protocol, Section 13.

Note: Changes in source of calcium (e.g., a change from calcium carbonate to citrate) need only be recorded on Form 5. Form 72 does not need to be completed in this case.

Item 12: Altered Sodium Prescription

- a) Enter reason for adjustment (1-4). If "4" is entered, 12b-d may be left blank. Discuss sodium adjustment with the physician.

- b) If the adjustment in the sodium prescription is to be the recommended 30% reduction in intake, enter the average urine sodium excretion (mEq) from the last three visits and calculate as noted on the form. An adjustment other than 30% may be used if clinically appropriate. In this case, follow this example:

$$\frac{\text{Average Urine Sodium Excretion from the Last Three Visits}}{\text{mEq}} \times 23 \times \frac{0.75}{\text{Atomic Weight}} = \text{This constitutes a reduction of 30\%}$$

0.80
This constitutes
a reduction of 20%

There is no data entry range check on the number of milligrams of sodium per day.

- c) If a different adjustment is to be implemented, enter up to 20 characters to note the reason example:
(comment: or 20% reduction used)
- d) Enter the altered prescription (mg/day) from either 12b or 12c. The prescription should not be below 1200 mg per day.

Item 13: Altered Alcohol Intake

- a) Enter 1=Yes or 2=No. If "2" is entered, 13b may be left blank.
- b) Enter the altered number of alcohol equivalents per day as recommended after consultation with the physician. Two alcohol equivalents are recommended however there is no data entry range check on the number of drink equivalents that you determined.

One alcohol equivalent=
1 1/2 oz. 80 proof distilled spirits
4 oz. dinner wine
12 oz. beer

Item 14: Altered Dietary Potassium Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, item 14b may be left blank.
- b) Enter the altered potassium prescription (physician prescription) in mg/day.

Item 15: Altered Magnesium Supplement Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, item 15b may be left blank.
- b) Enter the altered magnesium supplement prescription in mg/day.

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Item 16: Vitamin A Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, items 16b-d may be left blank.
- b) Indicate if a supplement is being prescribed (1=Yes, 2=No).
- c) If a supplement is being prescribed, enter the amount in IU/day. If a supplement is not being prescribed, enter "0".
- d) Code whether the patient has been counseled to increase Vitamin A intake solely from dietary sources, rather than from a supplement, by entering 1=Yes or 2=No.

Item 17: Altered Iron Supplement Prescription

- a) Enter 1=Yes or 2=No. If "2" is entered, item 18b may be left blank.
- b) Enter the altered iron supplement prescription in mg elemental Fe/day.
- c) Code and enter the type of iron supplement:
 - 1 = ferrous sulfate
 - 2 = ferrous fumarate
 - 3 = polysaccharide - iron complex

Item 18: Altered Percent of Calories from Fat

- a) Enter 1=Yes or 2=No. If "2" is entered, item 18b may be left blank.
- b) Enter the altered percent of calories from fat. The altered percent should be as low as feasible while keeping in mind protein and calorie goals. Recommended is less than 45%.

Item 19: Altered Percent of Calories from Carbohydrates

- a) Enter 1=Yes or 2=No. If "2" is entered, item 19b may be left blank.
- b) Enter the altered percent of calories from carbohydrates. Recommended is 45% to 60%; assess diagnosis and ability to maintain study goals with altered prescription to determine percent.

Item 20: Other Dietary Adjustments

- a) Enter 1=Yes or 2=No.
- b) If dietary changes other than those noted above were made, enter up to 20 characters to describe.

For DCC Use Only
Rev. 4 7/15/91

E ___
V ___
T ___



Modification of Diet in Renal Disease Study Special Dietary Considerations Form

Purpose: To provide a calculation and summary of any changes to the Study Diet, Dietary Supplements, or Prescriptions.

To be completed by the dietitian ONLY for patients who require changes in diet prescription due to Action Items or additional dietary considerations at any time during Follow-Up. (Note: This form should be entered into Datalex)

When medications are changed be sure to indicate on Form 5.

To complete this form you will need the DCC Flow Sheet, the Nutrient Summary Report from the NCC and the Dietary Information Summary Report.

FORM # 72

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center
- 4. a. Date of visit at which this prescription is given..... / /
- b. Visit Type E
- c. Visit Number.....
- 5. Standard Body Weight (kg).....
- 6. Randomization Diet Assignment from DCC (K, L, M).....
- 7. Blood Pressure Group Assignment.....
- 8. **Altered Protein Prescription**
For patients with Action Items for serum albumin or transferrin. Also for Diet K patients not taking keto acids whose unadjusted EPI is <0.40 g/kg/day. (Must be reviewed by Compliance Committee.) See Protocol Section 13 and Instructions for Form #72, for calculations.
 - a. Is protein prescription being altered? (1 = yes, 2 = no).....
 - If no, skip to item 9.
 - b. Altered Protein Prescription (g/kg/day).....
 - c. Portion of Altered Protein Prescription that must be High Biological Value. If none, enter "0"
- 9. **Altered Phosphorus Prescription**
For patients with an Action Item for serum phosphorus > 4.5 mg/dl or < 2.5 mg/dl - See Protocol Section 13.
 - a. Is phosphorus prescription being altered? (1 = yes, 2 = no).....
 - If no, skip to item 10.

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Modification of Diet in Renal Disease Study Special Dietary Considerations Form

9. (Continued)

Altered Phosphorus Prescription (mg/day)

b. _____ mg x _____ = _____
Lower range Std body wt. (kg)
of Altered
Phosphorus Rx
(if applicable)

c. _____ mg x _____ = _____
Upper range
of Altered
Phosphorus Rx

10. Altered Calorie Prescription

For patients with these Action Items (See Protocol Section 13): undesired weight loss or weight gain, recommended weight loss or weight gain, declining or low serum albumin or transferrin, or other reasons noted below in 10c.

a. Is calorie prescription being altered? (1 = yes, 2 = no)..... _____

If no, skip to item 11.

b. Review Study Diet Calorie Prescription - See Form 71 (item #5f)

i. Minimum Diet Calorie Prescription (kcal/day) _____

ii. Maximum Diet Calorie Prescription (kcal/day)..... _____

c. Code reason for calorie adjustment..... _____

- | | |
|--|---------------------------|
| 1 = Recommended weight loss | 5 = Diabetes management |
| 2 = Recommended weight gain | 6 = Low serum albumin |
| 3 = Recommended for weight maintenance | 7 = Low serum transferrin |
| 4 = Blood pressure management | 8 = Other (Specify) |

(20 characters maximum)

d. Altered Calorie Prescription (kcal/day) based on above considerations and clinical judgment.

i. Minimum Altered Diet Calorie Prescription (kcal/day)..... _____

ii. Maximum Altered Diet Calorie Prescription (kcal/day)..... _____

11. Altered Calcium Supplement Prescription

For patients with Action Items for low or high serum calcium, low dietary calcium intake, or other reason.

Note: Changes in calcium source (e.g., carbonate to citrate) need only be recorded on Form 5.

a. Is calcium prescription being altered? (1 = yes, 2 = no)..... _____

If no, skip to item 12.

i. For patient with action items for low or high serum calcium or low dietary intake (1 = yes, 2 = no)..... _____

**Modification of Diet in Renal Disease Study
Special Dietary Considerations Form**

12. (Continued)
d. Sodium prescription (mg/day)*
* Sodium prescription should not be below 1200 mg per day.
13. **Altered Alcohol Intake**
a. Is reduction necessary for blood pressure management or other conditions? (1 = yes, 2 = no)
If no, skip to item 14.
b. If yes: Number of alcohol equivalents per day
Limit intake to two or fewer alcohol equivalents per day (see Instructions for Form #72) or as recommended by physician.
14. **Altered Dietary Potassium Prescription**
For patients with an Action Item for high serum potassium. See Protocol section 13. Also if there is a specific physician prescription for potassium.
a. Is potassium prescription being altered? (1 = yes, 2 = no)
If no, skip to item 15.
b. Altered Potassium Prescription (mg/day)
15. **Magnesium Supplement Prescription**
For patients with an Action Item for low serum magnesium. See Protocol section 13.
a. Is magnesium prescription being altered? (1 = yes, 2 = no)
If no, skip to item 16.
b. Magnesium supplement (mg/day)
16. **Vitamin A Prescription**
For patients with an Action Item for low average daily dietary intake of vitamin A and carotene (<3300 IU/day). See Protocol and Manual of Operations Chapter 1.
a. Is Vitamin A prescription being altered? (1 = yes, 2 = no)
If no, skip to item 17.
b. Is a supplement being prescribed? (1 = yes, 2 = no)
c. If yes, indicate IU/day
d. Is patient being counseled to increase intake via dietary sources? (1 = yes, 2 = no)
17. **Altered Iron Supplement Prescription**
For patients with an Action Item for low serum iron or other reason.
See Protocol section 13.
Note: Changes in Iron source (e.g., sulfate to fumarate) need only be recorded on Form 5.
a. Is iron supplement prescription being altered? (1 = yes, 2 = no)
If no, skip to item 18.
b. Altered iron supplement (mg/day elemental Fe)

Modification of Diet in Renal Disease Study
PILL COUNT FORM

This form is used to record keto acid supplements given and to evaluate adherence to prescription.

Page 1 of this form should be completed by either the GFR Technician, Study Coordinator, Data Entry Clerk or Dietitian.

Page 2 may be completed by any noted above but, preferably, by the Pharmacist.

Careful review of this form is very important. At time of data entry, Datalex will calculate all figures in the EQUIVALENTS column of item 6 and all parts of items 6c, e, and f.

If a visit is missed completely, DO NOT complete Form 73. Wait until the patient does come and complete the form then.

If a patient comes and does not bring in his/her pills you must still complete the form, indicating this occurrence by entering -9 for items 6a or b, as appropriate.

Page 1 of FORM:

ITEM

INSTRUCTIONS

4a

Enter the date of the last scheduled monthly visit which patient attended. Enter corresponding visit number.

5d

Enter the number of days between last visit patient attended and this visit. This should be the number of days percent adherence is calculated from. If this visit is held in the morning, then be sure it is not counted as a day to have taken pills. You may have to adjust for half days.

Page 2 of FORM:

ITEM 6: Item 6 consists of three columns, one for each of keto acid packets, tablets, and equivalents. All values in the equivalents column will be calculated automatically by Entrypoint and will be skipped during data entry. Complete BOTH of the packet and tablet columns, handling each subitem as follows:

ITEM

INSTRUCTIONS

6a

Enter the number of packets/tablets the patient had in their possession at the end of the last visit. This will equal Item 6b plus Item 6g from last visit's Form 73, plus

Modification of Diet in Renal Disease Study
PILL COUNT FORM

ITEM

INSTRUCTIONS

any packets/tablets dispensed between the visits for patients who run out. If the patient is not prescribed one type, enter 0. If the patient forgot to bring the tablets/packets, enter -9. These values are required.

- 6b Enter the number of packets/tablets the patient returned at this visit. If the patient is not prescribed one type, enter 0. If the patient forgot to bring the tablets/packets, enter -9. These values are required.
- 6c The difference between packets/tablets in possession at end of last visit and returned at this visit will be calculated (a - b). This value is calculated by Entrypoint and will be skipped during entry. If a or b = -9, c will equal -9 also.
- 6d Enter the number of packets/tablets prescribed to be taken by the patient per day. If the patient is not prescribed one type, enter 0. These values are required.
- 6e The goal will be calculated as the daily prescription times the number of days between this visit and last visit (d x Item 5d). This value is calculated by Entrypoint and will be skipped during entry.
- 6f Percent adherence is calculated as the number of packets/tablets taken divided by the goal, times 100 (c/e x 100). Adherence is calculated for keto acid equivalents only. This value is calculated by Entrypoint and will be skipped during entry. If the number taken is -9, adherence will be -9 also.
- 6g Enter the number of packets/tablets newly dispensed to the patient at this visit. Do not include any packets/tablets that are reissued. If one type is not dispensed, enter 0. These values are required.

[]

For DCC Use Only
Rev. 4 4/2/90

E ___
V ___
T ___

Form # 73
Page 1 of 2



Modification of Diet In Renal Disease Study Pill Count Form

Purpose: To record dietary supplements given and evaluate adherence to prescription.

To be completed by Pharmacist, GFR Technician, Study Coordinator, Data Entry Clerk or Dietitian.

This form is to be completed at follow-up visit 2 and each visit thereafter except follow-up visit 2a, for Diet K patients only.

Questions 1 - 4 and 6 are to be completed at each follow-up visit (referred to here as the "last visit"). The remainder of the form is to be completed at the next follow-up visit (referred to here as "this visit").

Note: This form should be entered into Datalex.

FORM # Z 3

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center
- 4. a. Date of last visit.....
- b. Visit Type.....E
- c. Visit Number.....
- 5. a. Date of this visit.....
- b. Visit Type.....E
- c. Visit Number.....
- d. Number of days between last visit and this visit.....

Modification of Diet in Renal Disease Study Pill Count Form

	Keto Acid PACKETS	Keto Acid TABLETS	Keto Acid EQUIVALENTS
6. a. In possession at end of last visit.....	_____	_____	_____
b. Returned at this visit.....	_____	_____	_____
c. Taken between last visit and this visit (a - b).....	_____	_____	_____
d. Prescription per day.....	_____	_____	_____
e. Goal: Number of days (Item 5d) x d.....	_____	_____	_____
f. Percent adherence: (c / e) x 100	_____	_____	_____
g. Dispensed at this visit	_____	_____	_____
101. Date form completed.....	_____	_____/_____/_____	_____
102. Certification number of dietitian completing or reviewing this form	_____	_____	_____
103. Date form entered.....	_____	_____/_____/_____	_____
104. Certification number of data entry person	_____	_____	_____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. *Do not send this form to the NCC.* Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Modification of Diet in Renal Disease Study

Instructions for completing Form 74

DIETARY SATISFACTION QUESTIONNAIRE

- PURPOSE
1. To assess and monitor changes in the degree of satisfaction with the quantity and quality of foods in the patient's diet. To assess and monitor problems in planning and preparation of the diet, attitudes toward the diet, and acceptability of the diet.
 2. To serve as a basis for evaluating changes in the patient's diet and the effect these have had on the enjoyment of eating.
 3. To provide a specific opportunity for the patient to summarize his/her feelings about his/her diet.

COMPLETED BY: The patient at Baseline Visit 0, Follow-Up Visit 6, Follow-up Visit 12 and annually thereafter. In addition to visit types B and F, use K for post stop point Study C visits. Visit numbers must end in .0.

INSTRUCTIONS:

1. To reduce the possibility of bias, it is suggested that the study coordinator, (or someone whom she/he designates), rather than the dietitian review this form with the patient. Explain the form by using the example at the beginning of the form.
2. The study coordinator, or designate, will ask the patient to complete this form as honestly as possible based on his/her current feelings about his/her eating habits over the past time period.
3. Suggest that there are NO right or wrong answers to these questions.
4. Inform the patient that he/she will be asked to complete the form at Baseline Visit 0, Follow-Up Visit 6, 12 and annually thereafter.

- 5. Ask the patient not to put his/her name on the form for reasons of confidentiality. Spaces for the patient ID number are included.
- 6. Ask the patient to notice a few questions in particular:
 - a) Questions 6,7,8,9 - check the appropriate blank if they do not eat that meal.
 - b) Question 20 - write in the number of hours per day spent in meal planning and preparation.
 - c) Question 21 and 22 - give the patient an example of a special food product the patient might use, such as "light" mayonnaise or low calorie salad dressing. Ask the patient to write in any special food products and to ignore the coding section on the right.
- 7. Code Special Food Products in questions 21 and 22 using the following codes: (only code low protein food products)

LO-PRO Imitation Dairy Drink Mix.....	01
Kingsmill Unimix Baking Mix.....	02
Wel-Plan Cream Filled Vanilla Wafers.....	03
LO-PRO Rice Starch Bread Pre-baked.....	04
Prono Gelled Dessert Mix.....	05
Wel-Plan--pasta (spaghetti, macaroni).....	06
Aproten Rusks.....	07
Med-Diet Chocolate Chip Cookies.....	08
Med-Diet Spice Cookies.....	09
Ratatouille (R & D Labs).....	10
Aproten pasta (tagliatelle, ditalini, rigatini, anellini).....	11
R+D Labs Creamy Lemon Sauce.....	12
R+D Labs Garlic Herb.....	13
R+D Labs Tomato Sauce.....	14
other low protein sauce.....	15
other low protein bread.....	16
other low protein pasta.....	17
other low protein baking mix.....	18
other low protein cookies.....	19

other low protein gelled dessert mix.....20
 low protein crackers.....21
 low protein wheat starch.....22
 low protein rice flour.....23

Non-dairy liquid creamer (any brand).....24
 Non-dairy powdered creamer (any brand).....25
 Non-dairy whipped topping.....26
 Non-dairy imitation ice cream.....27
 other non-dairy substitutes.....28
 Cheddar cheese sauce mix.....29
 Apple chips/peach/pear.....30
 Low protein rice.....31
 Low protein porridge.....32
 Country stew with beef.....33
 Hearty corn chowder.....34
 Pasta alfredo with bacon.....35
 Oriental style rice.....36
 Go.....37
 Carnation Instant Breakfast.....38
 Pasta Buitoni.....39

8. At the Baseline 0 visit, ask the patient to complete the form only up to question number 24. After randomization, at Follow-Up Visits 6, 12, etc., ask the patient to complete all of the form including questions 24 through 30. Only Diet K patients need to complete questions 26 through 30.
9. For question number 25 regarding out of pocket costs of foods, ask the patient to circle the number which best corresponds to their current spending for food. Write their numerical response in the blank in the right margin for DCC coding.

Example: If you spent more. 2

1. up to \$5.00 per week more
2. \$5.01 to \$10.00 per week more
3. \$10.01 to \$20.00 per week more
4. over \$20.00 per week more

For DCC Use Only
Rev. 4 10/4/90

E ___
V ___
T ___

Form # 74
Page 1 of 5



Modification of Diet in Renal Disease Study Dietary Satisfaction Questionnaire

Purpose: To assess and monitor changes in the degree of satisfaction with the quantity and quality of foods in the patient's diet. To assess and monitor problems in planning and preparation of the diet, attitudes toward the diet, and acceptability of the diet. To serve as a basis for evaluating changes in the patient's diet and the effect these have on the patient's enjoyment of eating. To provide a specific opportunity for the patient to summarize his/her feelings about his/her diet.

To be completed by the patient at Baseline Visit 0, Follow-Up Visit 6, 12 and annually thereafter.

Procedure: The form is to be explained to the patient by the designated reviewer using the example at the beginning of the form. The form is reviewed for completeness.

FORM # Z 4

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center
- 4. a. Date of visit..... / /
- b. Visit Type (B = baseline, F = follow-up)
- c. Visit Number.....
- 5. Diet assigned (1 = Diet K, 2 = Diet L, 3 = Diet M, 4 = Baseline)

- 101. Date this form completed..... / /
- 102. Certification number of person reviewing form
- 103. Date form entered..... / /
- 104. Certification number of data entry person

Modification of Diet in Renal Disease Study Dietary Satisfaction Questionnaire

Please answer these questions to help us learn more about how you feel about what you eat.

EXAMPLE:

In general, to what degree do you like the taste of spaghetti?

Dislike extremely	1	2	3	4	5	Like very much
-------------------	---	---	---	---	---	----------------

Below is a list of questions to which there are no right or wrong answers. Please circle the number which best corresponds to your current feelings. Consider your eating habits over the past four months before answering these questions.

1. Rate your overall satisfaction with the way you are currently eating:

Dislike extremely	1	2	3	4	5	Like very much
-------------------	---	---	---	---	---	----------------

2. How often are you hungry?

Hungry often	1	2	3	4	5	Almost never hungry
--------------	---	---	---	---	---	---------------------

3. How would you describe your appetite?

Poor	1	2	3	4	5	Excellent
------	---	---	---	---	---	-----------

4. In general, are you satisfied with the taste of the food you are currently eating?

Not satisfied	1	2	3	4	5	Very satisfied
---------------	---	---	---	---	---	----------------

5. In general, are you satisfied with the amount of food you are currently eating?

Not enough	1	2	3	4	5	Too much
------------	---	---	---	---	---	----------

6. a. Check here if you do not eat Breakfast and go on to question 7.

- b. Are you satisfied with the amount of food you eat for BREAKFAST?

Not enough	1	2	3	4	5	Too much
------------	---	---	---	---	---	----------

7. a. Check here if you do not eat Lunch and go on to question 8.

- b. Are you satisfied with the amount of food you eat for LUNCH?

Not enough	1	2	3	4	5	Too much
------------	---	---	---	---	---	----------

8. a. Check here if you do not eat Dinner and go on to question 9.

- b. Are you satisfied with the amount of food you eat for DINNER?

Not enough	1	2	3	4	5	Too much
------------	---	---	---	---	---	----------

**Modification of Diet in Renal Disease Study
Dietary Satisfaction Questionnaire**

9. a. Check here if you do not eat Snacks and go on to question 10.

b. Are you satisfied with the amount of food or beverage you eat for SNACKS?

Not enough	1	2	3	4	5	Too much
------------	---	---	---	---	---	----------

10. How different do you feel your eating pattern is from what other people eat?

Very different	1	2	3	4	5	Not different at all
----------------	---	---	---	---	---	----------------------

11. How do you feel about other people knowing you will be or are currently changing your eating habits?

It bothers me quite a lot	1	2	3	4	5	I don't mind at all
---------------------------	---	---	---	---	---	---------------------

12. Do other people seem to be bothered by the fact you may eat differently than they do?

They seem to be bothered quite a lot	1	2	3	4	5	They don't mind at all
--------------------------------------	---	---	---	---	---	------------------------

13. Does eating out in restaurants cause you difficulty?

It causes me a lot of difficulty	1	2	3	4	5	It is not difficult
----------------------------------	---	---	---	---	---	---------------------

14. Does eating out at someone else's home cause you difficulty?

It causes me a lot of difficulty	1	2	3	4	5	It is not difficult
----------------------------------	---	---	---	---	---	---------------------

15. How much does how and what you eat interfere with other activities in your life?

It interferes a lot	1	2	3	4	5	It doesn't interfere at all
---------------------	---	---	---	---	---	-----------------------------

16. How much do you think what you eat affects your health?

No affect	1	2	3	4	5	It affects it a lot
-----------	---	---	---	---	---	---------------------

17. To what degree do you feel that making changes in your diet helps to improve how you feel?

Does not help at all	1	2	3	4	5	Helps a lot
----------------------	---	---	---	---	---	-------------

18. How difficult do you (or whomever does the shopping) find food shopping?

Very difficult	1	2	3	4	5	Very easy
----------------	---	---	---	---	---	-----------

**Modification of Diet in Renal Disease Study
Dietary Satisfaction Questionnaire**

19. How difficult is it to plan and prepare your meals?

Very difficult	1	2	3	4	5	Very easy
----------------	---	---	---	---	---	-----------

20. How much time, on average, is involved in planning, shopping, and preparing your meals? (hours per day)

21. Are there any special food products which you currently use and enjoy? (Staff person needs to enter the food codes.) (Y/N).....

If no, skip to item 22. If yes, specify:

- a. _____
- b. _____
- c. _____

22. Are there any special food products you have tried but do not enjoy? (Staff person needs to enter the food codes.) (Y/N).....

If no, skip to item 23. If yes, specify:

- a. _____
- b. _____
- c. _____

23. Are there any specific problems, additional comments or suggestions you would like to make about your current eating pattern, nutritional supplements, or special food products?

For patients who have been randomized into the MDRD Study Follow Up:

24. How do you enjoy eating now as compared to how you ate in the past (before you joined the MDRD Study)?

I liked my <u>previous</u> eating pattern much better	1	2	3	4	5	I like my <u>present</u> eating pattern much better
---	---	---	---	---	---	---

Modification of Diet in Renal Disease Study Dietary Satisfaction Questionnaire

25. Since you began your MDRD Study diet, do you spend more or less out of your own pocket on food than you did before beginning the diet (excluding any supplements you might receive from the clinic)? Indicate the number which best corresponds to your current spending.....
- 1 = I spend more
 - 2 = I spend less
 - 3 = I spend about the same
- a. If you spend more than you did, indicate the number which best corresponds to your current spending.....
- 1 = Up to \$5.00 per week more
 - 2 = \$5.01 to \$10.00 per week more
 - 3 = \$10.01 to \$20.00 per week more
 - 4 = Over \$20.00 per week more
- b. If you spend less than you did, indicate the number which best corresponds to your current spending.....
- 1 = Up to \$5.00 per week less
 - 2 = \$5.01 to \$10.00 per week less
 - 3 = \$10.01 to \$20.00 per week less
 - 4 = Over \$20.00 per week less

If not on Diet K, STOP.

For patients on Diet K only:

26. How difficult is it for you to remember to take the keto acids?

Very difficult	1	2	3	4	5	Very easy
----------------	---	---	---	---	---	-----------

27. How difficult is it for you to actually take the keto acids?

Very difficult	1	2	3	4	5	Very easy
----------------	---	---	---	---	---	-----------

28. How important do you think the keto acids are to your health?

Not very important	1	2	3	4	5	Very Important
--------------------	---	---	---	---	---	----------------

29. How much do you think the keto acids help to improve how you feel?

Do not help at all	1	2	3	4	5	Help a lot
--------------------	---	---	---	---	---	------------

30. In general, are you satisfied with the taste of the keto acids?

Not satisfied at all	1	2	3	4	5	Very satisfied
----------------------	---	---	---	---	---	----------------

**Instructions
for
Counseling Summary Form
(Form 76)**

Purpose and Overview of Form Use

Purpose

- To summarize patient progress, problems, and strategies.
- To plan goals for next visit.
- To report compliance strategies and counseling activities used by dietitians.
- To document the action taken to remediate adherence problems.
- To focus intervention on compliance to the protein prescription with secondary emphasis on compliance to other interventions: sodium, supplements, calories, high biological value protein, etc.
- To inform the NCC of action taken to maximize compliance.
- To provide information and background to the NCC and Compliance Committee when their consultation is planned to help remediate out-of-range Four-Month EPI(UNA) values or aminogram data.

Overview of Form Use

(Following is a brief overview of how the form is used; specific instructions start on the next page.)

This form is completed by the dietitian at each Follow-Up visit, including dietitian-only visits (1A and 2A).

In preparation for a visit or contact, review the following:

- | | |
|---|--|
| <input type="checkbox"/> Urine Report | <input type="checkbox"/> Pill Adherence Data (Pill Count Form, Supplement Calendar, other) |
| <input type="checkbox"/> Fast Report Form (amino acid data) | <input type="checkbox"/> Compliance Flowsheet(s) |
| <input type="checkbox"/> Food/Nutrient Intake
(Self-Monitoring, Three-Day Food Record, or Nutrient Summary Report) | <input type="checkbox"/> Counseling Summary Form (Form 76) |
| <input type="checkbox"/> How Is It Going? graph | <input type="checkbox"/> Counseling Summary Report |
| <input type="checkbox"/> Weight changes since previous visit | <input type="checkbox"/> Counseling Assessment Report |
| <input type="checkbox"/> Biochemistry Flowsheet(s) | <input type="checkbox"/> Special Dietary Considerations Form (Form 72) |
| | <input type="checkbox"/> Dietary Satisfaction Report |
| | <input type="checkbox"/> Action Item Flowsheets |

For Follow-Up Visits 1, 1A, 2, and 2A, complete items 1-6 and 8-12 only. At these visits the form is used during/following the visit (in contrast to other visits where it is initiated *before* the visit--see below).

Beginning with *Follow-Up Visit 3* (and for each visit thereafter), use the form in this manner:

- Review Urine Report and aminogram data from **last** visit (within 5 to 7 days of the visit), and use data to complete items 7a through 7h. Complete 7d for patients on Diet K only.
- Within 12 days after the last visit contact the patient if the EPI(UNA) and/or aminogram is out of range as described in Manual of Operations, Chapter 1, Section 9. Summarize contact in item 7h.
- If the visit is missed, hold the form and complete the remaining items at the next visit.
- The form is entered into Datalex after the visit.

2.286

To Complete the Form

- 1-3. Enter the patient's identification number, name code, and clinical center.
- 4. a. Record the date the visit is held with the patient.
- b. Visit or Contact Code
 - . 0 A whole number, such as 3.0, is used to designate a regular Follow-Up visit held at the center.
 - . 5 Use the codes 1.5 or 2.5 when a 1A or 2A visit, respectively, is held at the center.
 - . 7 Use the code xx.7 to designate a group visit.
 - . 9 Use the codes 1.9 or 2.9 when a 1A or 2A visit, respectively, is conducted by telephone.
- 5. Code diet assignment using 1=K; 2=L; 3=M.
- 6. Code (1) for moderate MAP goal or (2) for low MAP goal.

Before the Visit (Do not complete at Visits 1, 1A, 2, or 2A.)

- 7. Use item 7 to summarize patient compliance based on data from the **last** visit. You will need the Urine Report (and aminogram data for Diet K patients) from the last visit to complete this item.
 - a. **Percent Agreement of EPI (UNA) with Protein Prescription:** EPI(UNA) (%)
(Leave blank if urine not collected.)

Enter here the degree to which the EPI(UNA) agrees with the protein prescription based on the urine returned at the **last** visit. The following equation should be used:

$$\frac{\text{EPI (UNA)}}{\text{Protein Rx (gm/kg/day)}} \times 100$$

- b. **Percent Agreement of Reported Protein with Protein Prescription:** Reported Protein (%)

Enter here the degree to which the reported protein (mean protein from the three-day food record) agrees with the protein prescription. Use the value reported on last month's Compliance Flowsheet (see row labeled "% agreement with study rx" on flowsheet). When values for reported protein are unavailable (for example, at even-numbered visits), the percent agreement should be calculated using an estimate of protein intake based on analysis of the most recently available data (self-monitoring records, 24-hour recall, or three-day food record). If not possible to determine, leave blank. The following equation should be used:

$$\frac{\text{Reported Protein (gm/kg/day)}}{\text{Protein Prescription (gm/kg/day)}} \times 100$$

- c. **Adherence Categories**

Enter the number of the adherence category that best describes the patient's current or most recent level of adherence. (See Manual of Operations, Volume 1, Chapter 1, Section 9 for definition of Adherence Categories.) Refer to the most recent Monthly Compliance Flowsheet for the adherence category. (If necessary, determine the adherence category from locally derived or NCC report of protein intake.) If it is not possible to determine the category, leave blank.

- d. (Diet K only) Evaluate aminogram and pill count (and/or records of self-monitoring such as Keeping Track, Supplement Calendar, etc.) for consistency between the data. Leave blank if not on Diet K or data not available.
- e. Code 1=Yes or 2=No if last visit was missed. If yes, record the reason for the missed visit (such as: illness, "no show", vacation, etc.).
- f. Code 1=Yes or 2=No if patient was discussed at study team meeting since the visit.
- g. Code whether a telephone contact was made in response to an EPI (UMA) or aminogram out of range. (1=Yes, 2=No)
- h. Telephone Contact Summary

If a telephone call was made since the last visit, summarize the discussion with the patient including problem(s) identified and strategies developed. Complete Action Item Report (Form 23) if EPI (UMA) or aminogram is out of range. (Leave blank if call was not made.)

At the Visit

8. Patient Achievements

During the visit encourage the patient to discuss successes, achievements, and progress in working toward or maintaining dietary goals since the last visit. Refer to the phrases below and use up to four codes to generally describe the patient's perception of his progress. Include your assessment of the patient's achievements (even if they are not specifically stated by the patient). Additional lines for listing specific achievements and comments are included on Form 76.

Achievement Codes

1. Patient is pleased with progress.
2. Patient met or partially met goals set at last visit or contact.
3. Patient has not made any progress.
4. Other (list other positive statements in comments section of form).

9. Self-Monitoring Activities

The "standard MDRD technique" of self-monitoring (coded in item 9a below) asks the patient to keep a written record of what he has eaten and to use the Protein Counter to look up the nutrient content of foods. Later in intervention the patient may need different, simpler, or more streamlined methods of self-monitoring, such as checking foods eaten from preplanned menus or food group lists; recording foods eaten and, with the dietitian at the clinic visit, using CDDT to analyze intake; using the MDRD Daily Food Guide; or using other means of keeping track of intake. These abbreviated methods of self-monitoring (coded in item 9b below) are not considered the "standard MDRD technique." See Manual of Operations, Dietitians Chapter, for a complete discussion of self-monitoring.

- a. Enter patient's use of the "standard MDRD technique" to self-monitor protein in days per week ranging from 0 to 7. If patient is using the standard technique to self-monitor less regularly (for example, only two or three times a month), enter the code 9. If patient is not self-monitoring at all, enter 0.
- b. Enter patient's use of other methods to self-monitor protein in days per week ranging from 0-7. Please describe the method(s) used in the comments section below. If patient is using these methods infrequently (for example, two or three times a month), enter the code 9. If patient is not self-monitoring, enter 0.

11. Dietitian Counseling Activities

Summarize counseling activities that you included during this contact or that you plan to use in the next month. List counseling activities by entering in the blanks on the form the code(s) that correspond to the phrases below. Enter codes starting from the left; blanks not used may be left empty. Limit to 10 codes.

Counseling Activities

- | | |
|--|--|
| 1. introduced or reviewed the Study Diet Prescription | 19. provided guidelines for cholesterol/fat modification |
| 2. provided counseling regarding pill compliance | 20. provided guidelines for phosphorus modification |
| 3. provided feedback based on self-monitoring and/or Three-Day Food Record | 21. provided guidelines for potassium modification |
| 4. reviewed nutrient values of foods | 22. provided guidelines for increasing calories |
| 5. reviewed Compliance or Biochemistry Flowsheet(s) | 23. provided guidelines for decreasing calories |
| 6. introduced or updated How Is It Going? graph | 24. provided guidelines for increasing high biological value foods |
| 7. chose <u>not</u> to discuss EPI | 25. provided exercise guidelines |
| 8. provided new or more low protein food products | 26. conducted role-playing session |
| 9. provided new or additional recipes | 27. provided guidelines for relapse prevention |
| 10. provided additional menus | 28. worked, or will work, with family/significant other |
| 11. reviewed how to use Counter | 29. planned a special group activity |
| 12. reviewed label reading | 30. planned for increased telephone contact |
| 13. reviewed math skills | 31. will send reminders by phone or postcard |
| 14. reviewed weighing and measuring skills | 32. used, or will use, CDDT |
| 15. included a food tasting session | 33. referral made |
| 16. called restaurant for more information | 34. other (please specify in comments section) |
| 17. provided guidelines for protein modification | |
| 18. provided guidelines for sodium modification | |

12. Progress Notes

In this area on the form you can summarize in your own words anything about the contact or visit that was not included elsewhere on the form. This is a good place to include your assessment of the contact, your impression of the patient's attitude, and ideas of what you feel should be included in the next contact. Also include information that other dietitians will need to know.

Please be sure to conclude your note by listing in the section labeled "Plan" on the form goals set/strategies developed for the next month or next four-month period. Keep strategies developed measurable (so you can determine whether or not they worked), accomplishable by the patient, and significant enough to produce the desired effect. This section must be completed for regular Follow-Up visits and dietitian only visits.

Clinic progress notes with confidential information deleted may be substituted for this section; if so, a copy should be attached to the form sent to the NCC. (Please include in clinic progress notes a section similar to the "Plan" described above.) This section is not entered into Datalex.

* * * * *

**Items 13-16 completed at formal compliance assessment visits only
(F5, F9, F13, etc.).**

General Instructions for Items 13 through 16

Use items 13 through 16 to record your assessment of the patient in four areas: attitude, environment and social support, health, and socialization. A general question is given on the form for each assessment area to help direct your assessment.

For each assessment area:

1. Circle the number which best describes your assessment of the patient according to the scale on the form. Circle 1 only if the patient has no problems in that area; then go on to the next assessment area.
2. If you circled 2, 3, 4, or 5 on the scale list the possible patient problems within that assessment area by entering in the blanks on the form the code(s) that correspond to the possible problems listed below.
3. Additional lines for comments are included on Form 76 for each assessment area.

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13. Attitude Assessment

How does your MDRD eating pattern fit into your lifestyle at this time?

- a. Using the scale on the form, circle the number which best describes your assessment of the patient's attitude regarding his MDRD eating pattern. (Go on to item 14 if "1" is circled.)
- b. List possible problem areas by entering in the blanks on the form the code(s) that correspond to the phrases below. Enter codes starting from the left; blanks not used may be left empty. Limit to 10 codes.

Possible Problem Areas At This Time

- | | |
|---|---|
| 1. perceives diet as being too difficult or time-consuming | 6. does not wish to discuss condition, exhibits possible denial |
| 2. has inconsistent food intake | 7. is unwilling to self-monitor |
| 3. is unwilling to complete assignments or carry out strategies | 8. is overly compulsive about diet |
| 4. record/states only what dietitian "wants to hear" | 9. is unwilling to use low protein foods |
| 5. has given up | 10. resists eating up to or down to prescription |
| | 11. discouraged by increasing complexity of dietary regimen |
| | 12. other (please specify in comments section) |

14. Environment/Social Support Assessment

Please describe the help and support you get from your family, friends or people at work at this time.

- a. Using the scale on the form, circle the number which best describes your assessment of the patient's social support. (Go on to item 15 if "1" is circled.)
- b. List possible problem areas by entering in the blanks on the form the code(s) that correspond to the phrases below. Enter codes starting from the left; blanks not used may be left empty.

Possible Problem Areas At This Time

- | | |
|--|--|
| 1. lacks support at home | 4. has crisis/stress within the family |
| 2. lacks support of employer/coworkers/friends | 5. has financial concerns |
| 3. has had a change in primary food preparer/shopper | 6. has stress at work |
| | 7. other (specify in comments section) |

15. Health Assessment

Please describe how your overall health has influenced your appetite or eating pattern in recent weeks.

- a. Using the scale on the form, circle the number which best describes your assessment of how the patient feels his health influences his appetite and eating pattern. (Go on to item 16 if '1' is circled.)
- b. List possible problem areas by entering in the blanks on the form the code(s) that correspond to the phrases below. Enter codes starting from the left; blanks not used may be left empty. Limit to 10 codes.

Possible Problem Areas At This Time

- | | |
|---|--|
| 1. is frequently hungry | 8. has deteriorating kidney function |
| 2. has a low energy level | 9. has had a change in taste |
| 3. experiences early satiety/poor appetite | 10. has had weight loss |
| 4. feels food/calories prescribed excessive ("too much food") | 11. has had weight gain |
| 5. is anorexic | 12. is not taking keto acids/supplements as prescribed |
| 6. is depressed | 13. interfering blood pressure symptoms |
| 7. has had a short-term illness | 14. has problem related to another medical condition |
| | 15. other (specify in comments section) |

16. Socialization Assessment

Please tell me how your eating style at this time affects your motivation to attend social functions, to eat out, or to travel.

- a. Using the scale on the form, circle the number which best describes your assessment of the patient's management of social situations. (Go on to item 101 if '1' is circled.)
- b. List possible problem areas by entering in the blanks on the form the code(s) that correspond to the phrases below. Enter codes starting from the left; blanks not used may be left empty.

Possible Problem Areas At this Time

- | | |
|---|--|
| 1. dines out frequently | 4. drinks too much alcohol |
| 2. has interfering vacation/travel | 5. avoids eating out |
| 3. has had a change in frequency of social events | 6. weekend eating interferes |
| | 7. other (specify in comments section) |

.....
101-104. See Form #76.

Retain a copy of this form for your files. Please send original to the NCC.

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**Modification of Diet in Renal Disease Study
Counseling Summary Form**

FORM # Z 6

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center.....
- 4. a. Date of visit or contact..... / /
- b. Visit Type..... E
- c. Visit number or Contact Code.....
 - . 0 = Regular Follow-up Visit
 - . 5 = Regular Dietitian Only Visit
 - . 7 = Group Visit
 - . 9 = Dietitian Only Visit conducted by telephone
- 5. Diet Assignment (1 = K; 2 = L; 3 = M).....
- 6. MAP Goal (1 = moderate; 2 = low).....

PRIOR TO VISIT:

- 7. **Compliance Monitoring** (Based on data from last visit.)
Do not complete at Visits 1 through 2A.
 - a. Percent Agreement of EPI (UNA) with Protein Prescription:
EPI (UNA) (%).....
 - b. Percent Agreement of Reported Protein with Protein Prescription:
Reported Protein (%).....
 - c. Adherence Category.....
 - d. (Diet K only) Is aminogram data (see Fast Report Form) consistent with pill count
and/or other records of keto acid use? (1 = Yes, 2 = No).....
 - e. Was last visit missed? (1 = Yes, 2 = No).....
If yes, please record reason (not entered in Datalex).....
 - f. Was patient discussed at team meeting since the last visit? (1 = Yes, 2 = No).....
 - g. Was follow-up phone call made during the past month in response to EPI (UNA) or
aminogram out of range? (1 = Yes, 2 = No).....
 - h. Telephone Contact Summary (This section is not entered into Datalex)

**Modification of Diet in Renal Disease Study
 Counseling Summary Form**

AT FOLLOW-UP VISIT:

8. Patient Achievements

During the visit, encourage the patient to discuss successes, achievements, and progress in working toward or maintaining dietary goals since the last visit. Refer to the phrases in the instructions and use up to four codes to describe what the patient has discussed. Include your assessment of the patient's achievements (even if they are not specifically stated by the patient).

Code achievements using codes listed in Instructions..... _ _ _ _

Comments: (Not entered into Datalex.) _____

9. Self-Monitoring Activities

a. Number of days per week patient uses "Standard MDRD Technique" (See Instructions) to self-monitor protein (enter 0-7)..... _ _ _ _

b. Number of days per week patient uses other method(s) to self-monitor protein (See Instructions); (enter 0-7) _ _ _ _

c. Grams of protein per day as recorded on self-monitoring tool _ _ _ _

d. Code other nutrients being self-monitored (See codes list on Instructions for Form #76) _ _ _ _

Comments: (Not entered into Datalex.) _____

10. Skill/Knowledge Assessment

a. *Do you have evidence to suggest that the patient has sufficient skills and knowledge at this time to meet study goals?*

Has sufficient skills and knowledge	1	2	3	4	5	Lacks sufficient skills and knowledge
-------------------------------------	---	---	---	---	---	---------------------------------------

b. *If 1 is circled, go on to Question 11; if 2,3,4, or 5 is circled, code possible problem areas using corresponding codes listed in Instructions to Form 76.*

Comments: (Not entered into Datalex.) _____

**Modification of Diet in Renal Disease Study
Counseling Summary Form**

11. Dietitian Counseling Activities

Enter counseling activities that you included at this contact or that you plan to use in the next month. Use codes listed in Instructions to Form #76.

Comments: (Not entered into Datalex.) _____

12. PROGRESS NOTES: Please summarize session here. Be sure to conclude your note by listing in the section labeled "Plan" below Goals set/Strategies developed for the next month or next four-month period. (Clinic progress notes may be attached as a substitution for this section, however, please delete patient name and other confidential information.) This section is not entered into Datalex.

PLAN: Goals set/Strategies developed (See Instructions) _____

Modification of Diet in Renal Disease Study Counseling Summary Form

Items 13-16 are completed at Four-Month Compliance Assessment visits only: F5, F9, F13, etc. Please summarize major goals identified at four-month visit in Progress Notes (#12). Other visits go on to Item 101. Comments are not entered into Datalex.

13. Attitude Assessment

a. How does your MDRD eating pattern fit into your current lifestyle at this time?

Very positive attitude	1	2	3	4	5	Very negative attitude
------------------------	---	---	---	---	---	------------------------

b. If 1 is circled go on to Question (14); if 2,3,4, or 5 is circled, code possible problem areas using codes in Instructions

_____, _____, _____, _____, _____, _____, _____, _____
Comments: _____

14. Environment/Social Support Assessment

a. Please describe the help and support that you get from your family, friends, or from people at work at this time.

Excellent social support	1	2	3	4	5	Very little social support
--------------------------	---	---	---	---	---	----------------------------

b. If 1 is circled go on to Question (15); if 2,3,4, or 5 is circled, code possible problem areas using codes in Instructions

_____, _____, _____, _____, _____, _____, _____, _____
Comments: _____

15. Health Assessment

a. Please describe how your overall health has influenced your appetite or eating pattern in recent weeks.

Has very little effect	1	2	3	4	5	Has great effect
------------------------	---	---	---	---	---	------------------

b. If 1 is circled go on to Question (16); if 2,3,4, or 5 is circled, code possible problem areas using codes in Instructions

_____, _____, _____, _____, _____, _____, _____, _____
Comments: _____

**Modification of Diet in Renal Disease Study
Counseling Summary Form**

16. Socialization Assessment

a. Please tell me how your eating style at this time affects your motivation to attend social functions, to eat out, or to travel.

Eating pattern does not interfere with social activities	1	2	3	4	5	Eating pattern interferes greatly with social activities
--	---	---	---	---	---	--

b. If 1 is circled go on to Question (101); if 2,3,4, or 5 is circled, code possible problem areas using codes in Instructions

Comments: _____

- 101. Date this form completed..... _ / _ / _
- 102. Certification number of dietitian completing this form..... _____
- 103. Date form entered..... _ / _ / _
- 104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Nutrition Coordinating Center. Do not send this form to the DCC. Please use MDRD Study mailing labels:

MDRD Nutrition Coordinating Center
Department of Epidemiology
Graduate School of Public Health
University of Pittsburgh
130 DeSoto Street
Pittsburgh, PA 15261

Modification of Diet in Renal Disease Study Counseling Summary Form

10. SOCIALIZATION ASSESSMENT

Please tell me how you feel your eating style affects your motivation to attend social functions, to eat out, or to travel.

- a. Patient indicates he/she is able to manage most social situations or dining out. (1 = yes, 2 = no) Go on to 10b.....

Does the patient indicate or do you perceive that the patient has a problem in any of the areas listed below. Additional spaces are included for you to write in other problems. Limit each to twenty characters. (For the following: 1 = yes, this is a problem area, 2 = no, this is not a problem area. Leave blank if not discussed.)

POSSIBLE PROBLEM AREAS

- b. dines out frequently.....
- c. has interfering vacation/travel.....
- d. has had a change in frequency of social events.....
- e. drinks too much alcohol.....
- f. avoids eating out.....
- g. Other problems
Describe: _____
- h. Other problems
Describe: _____

11. SKILL/KNOWLEDGE ASSESSMENT

In your opinion, as a dietitian, do you feel the patient has sufficient skills and knowledge to carry out study goals?

- a. Patient has sufficient skills and knowledge. (1 = yes, 2 = no) Go on to 11b.....

Do you perceive that the patient has a problem in any of the areas listed below. Additional spaces are included for you to write in other problems. Limit each to twenty characters. (For the following: 1 = yes, this is a problem area, 2 = no, this is not a problem area. Leave blank if not discussed.)

POSSIBLE PROBLEM AREAS

- b. finds dietary restrictions too complex.....
- c. incomplete or inaccurate record keeping.....
- d. incomplete or inaccurate self-monitoring.....
- e. weighs and measures foods inaccurately.....

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Modification of Diet in Renal Disease Study Counseling Summary Form

11. (Continued)
- f. refuses to weigh and measure foods.....
 - g. does not record recipes completely or accurately.....
 - h. discriminates protein values poorly.....
 - i. underestimates protein intake
 - j. lacks understanding.....
 - k. unable to modify recipes or food preparation
 - l. does not do his own record keeping
 - m. has poor reading skills.....
 - n. has poor handwriting.....
 - o. has language or cultural barrier.....
 - p. Problems related to sodium intervention
 - Describe: _____
 - q. Problems related to supplement compliance
 - Describe: _____
 - r. Problems related to weight loss or weight gain.....
 - Describe: _____
 - s. Other.....
 - Describe: _____

12. Now that the patient has identified some factors that may be affecting his/her ability to comply, encourage the patient to develop goals or strategies to remediate the problem areas. Additional spaces are included so you can write in other strategies that the patient develops. Limit each to twenty characters. Use the following code to identify goals or strategies the patient currently uses or plans to use in the next month or until the next contact: 1 = yes - plans to use this strategy, or, 2 = no - the patient does not plan to use this strategy.

PATIENT STRATEGIES

- a. maintain frequency of self-monitoring.....
- b. increase frequency of self-monitoring
- c. self-monitor problem meal(s) only.....
- d. focus on weekend eating.....
- e. focus on dining out/social events strategies

**Modification of Diet in Renal Disease Study
Counseling Summary Form**

12. (Continued)
- f. increase time available to focus on meal planning/shopping....._____
 - g. increase time available to focus on meal preparation....._____
 - h. discuss goals and needs with spouse/significant other....._____
 - i. try additional low protein products....._____
 - j. try additional/new recipes....._____
 - k. try new convenience foods....._____
 - l. try meatless meals....._____
 - m. take lunch to work....._____
 - n. eat out less often....._____
- sodium specific strategies
- o. Describe: _____
 - p. Describe: _____
- fat/cholesterol reducing strategies
- q. Describe: _____
 - r. Describe: _____
- specific strategies to improve compliance to supplements
- s. Describe: _____
 - t. Describe: _____
- weight loss strategies (reduce calories)
- u. Describe: _____
 - v. Describe: _____
- weight gain strategies (increase calories)
- w. Describe: _____
 - x. Describe: _____

Modification of Diet in Renal Disease Study Counseling Summary Form

13. INTERVENTION MATERIALS

Indicate the code number of intervention materials used at this session. This code is found in the lower right hand corner of all intervention handouts. Please limit codes to fifteen.

- | | | |
|---------------|---------------|---------------|
| a. _____/____ | f. _____/____ | k. _____/____ |
| b. _____/____ | g. _____/____ | l. _____/____ |
| c. _____/____ | h. _____/____ | m. _____/____ |
| d. _____/____ | i. _____/____ | n. _____/____ |
| e. _____/____ | j. _____/____ | o. _____/____ |

14. DIETITIAN COUNSELING ACTIVITIES

Summarize counseling activities that you included at this contact or that you plan to use in the next month. (For the following: 1 = yes, was included or is to be implemented, 2 = no, not to be included.)

COUNSELING ACTIVITIES

- a. introduced or reviewed the Study Diet Prescription....._____
- b. provided counseling regarding pill compliance....._____
- c. reviewed Nutrient Summary Report(s)....._____
- d. reviewed Compliance Flowsheet(s)....._____
- e. reviewed Biochemistry Flowsheet(s)....._____
- f. provided new or more low protein food products....._____
- g. provided new or additional recipes....._____
- h. provided additional menus....._____
- i. provided guidelines for sodium modification....._____
- j. provided guidelines for cholesterol/fat modification....._____
- k. provided guidelines for phosphorus modification....._____
- l. provided guidelines for potassium modification....._____
- m. provided guidelines for increasing calories....._____
- n. provided guidelines for decreasing calories....._____
- o. provided guidelines for increasing high biological value foods....._____

Modification of Diet In Renal Disease Study Counseling Summary Form

14. (Continued)
- p. reviewed label reading
 - q. had patient demonstrate skills for you.....
 - r. provided a food tasting session
 - s. used a food demonstration session
 - t. planned for increased telephone contact
 - u. introduced or updated How is It Going?
 - v. used CDDT at the visit.....
 - w. will use CDDT after the visit.....
 - x. will send postcard reminders or other forms of mail contact.....
 - y. planned for a special meeting with study team or PI
 - z. planned for a special meeting with family/significant other.....
 - aa. planned a special group session.....
 - bb. planned a home visit
 - cc. planned a restaurant visit.....
 - dd. referred patient to another health professional/organization
 - ee. Other
 - Describe: _____
 - ff. Other.....
 - Describe: _____

15. **PROGRESS NOTES:** This section is not entered into Datalex.

**Modification of Diet in Renal Disease Study
Counseling Summary Form**

15. PROGRESS NOTES (Continued)

101. Date this form completed..... _ / _ / _
102. Certification number of dietitian completing this form..... _____
103. Date form entered..... _ / _ / _
104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center and send a copy to the MDRD Nutrition Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

MDRD Nutrition Coordinating Center
Department of Epidemiology
Graduate School of Public Health
University of Pittsburgh
130 DeSoto Street
Pittsburgh, PA 15261

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For DCC Use Only
Rev. 1 11/30/89

E ___
V ___
T ___

Form # 77
Page 1 of 1

MDRD

Modification of Diet in Renal Disease Study Patient Care Time Log

Purpose: To log dietitian time spent in patient care activities preparing for and at each visit. Time spent after the visit should be recorded on next month's form.

To be completed by the dietitian. (Note: This form should be entered into Datalex.)

FORM # Z Z

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of Visit..... / /
- b. Visit Type.....
- c. Visit Number.....

Time in Minutes

Subtotal

5. Preparation/Follow-up (without CDDT)								
6. Preparation/Follow-up (with CDDT)								
7. Actual Counseling (without CDDT)								
8. Actual Counseling (with CDDT)								
9. Food Record Doc. (with patient).....								
10. Food Record Doc. (without patient).....								
11. Charting in Patient Record.....								
12. Phone Calls with Patient.....								
13. Patient Conference								
14. Anthropometrics.....								
15. Other (20 characters maximum).....								

-
16. TOTAL (Time in Minutes).....
 17. TOTAL (hh:mm) (will match time entered on Form #04 Q40 or #05 Q16)... :
 101. Date this form completed..... / /
 102. Certification number of person filling out this form
 103. Date form entered..... / /
 104. Certification number of data entry person

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Modification of Diet in Renal Disease Study

NUTRITION HISTORY

- PURPOSE:
1. To provide background information relative to the social environment of food consumption, such as where and when food is eaten, who is involved in preparation, what facilities are available for food storage and preparation, whether the patient has particular food likes and dislikes.
 2. To assess the patient's experience with food/diet related issues.
 3. To evaluate the patient's willingness and ability to follow instructions and record information.

INSTRUCTIONS:

1. The Nutrition History Questionnaire Form is in two parts. Form 78-P is completed by the patient and is not coded. Form 78 is to be coded from the answers provided by the patient on Form 78-P and entered into Datalex.
2. Give Form 78-P to the patient at the Screening Visit. It is to be completed by the patient before the next visit.
3. Review Form 78-P with the patient to make sure it can be understood.
4. Attach a stamped addressed envelope for mailing to the Clinical Center or ask the patient to bring it to the next visit.
5. When the patient returns Form 78-P, code and complete Form 78 which is to be entered into Datalex. Enter the codes, as answered by the patient on Form 78-P, for questions 5, 6, 7, and 8. NOTE for item 8a and b (Form 78): If the answer to 8a (Does the patient live with other family members?) is yes yet the other member is, for example, an infant, item 8b is then not applicable. In such instances, leave item 8b blank.
6. Retain the Nutrition History Form 78-P in the patient's file.

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Handwritten scribble

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For DCC Use Only
Rev. 4 3/27/90

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V ___
T ___

Form # 78
Page 1 of 3

MDRD

Modification of Diet in Renal Disease Study Nutrition History Questionnaire

This form should be completed by transcribing the patient's responses to Form 78-P.
(Note: This form should be entered into Datalex)

FORM # Z 8

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date form given to patient.....
- b. Visit Type.....
- c. Visit Number.....
5. Has the patient followed a special diet in the past? (1 = yes, 2 = no).....

If no, skip to item 6. If yes, code which diet(s) were followed (1 = yes, 2 = no):

- a. Low calorie, weight loss.....
- b. Low fat/Low cholesterol.....
- c. Low protein.....
- d. Low sugar/Diabetic.....
- e. High fiber.....
- f. Low salt.....
- g. Low potassium.....
- h. Other:.....

Who taught the patient the diet(s)? (For the following: 1 = yes, 2 = no)

- i. Doctor.....
- j. Nurse.....
- k. Relative.....
- l. Dietitian.....
- m. No one.....
- n. Other (example: Weight Watchers):.....
- o. What was the last year the patient was on the diet?.....
- p. How long did the patient follow the diet? (Months).....

Modification of Diet in Renal Disease Study Nutrition History Questionnaire

6. Is the patient now following (or trying to follow) any special diet? (1 = yes, 2 = no) _____

If no, skip to item 7. If yes, code which diet(s) were followed (1 = yes, 2 = no):

30 Calorie Restriction →

30 Diet Restriction →

- a. Low calorie, weight loss.....
- b. Low fat/Low cholesterol.....
- c. Low protein.....
- d. Low sugar/Diabetic.....
- e. High fiber.....
- f. Low salt.....
- g. Low potassium.....
- h. Other: _____

Who recommended the special diet? (For the following, 1 = yes, 2 = no)

- i. Doctor.....
- j. Nurse.....
- k. Dietitian.....
- l. No one.....

Who taught the patient the diet(s)? (For the following, 1 = yes, 2 = no)

- m. Doctor.....
- n. Nurse.....
- o. Relative.....
- p. Dietitian.....
- q. No one.....
- r. Other (example: Weight Watchers): _____

s. When did the patient receive the instructions (approximate date)? ____/____/____

t. Does the patient have difficulty following this diet? (1 = yes, 2 = no) _____

If yes, please describe the difficulties:

**Modification of Diet in Renal Disease Study
Nutrition History Questionnaire**

7. a. Does the patient live with a spouse or significant other? (1 = yes, 2 = no)....._____

If no, skip to item 8a. If yes,

b. How supportive does the patient think his/her spouse/significant other/person(s) with whom he/she lives would be if he/she were asked to make changes in his/her diet? (Circle one number on the scale below.)

Not Supportive	1	2	3	4	5	Very Supportive
----------------	---	---	---	---	---	-----------------

8. a. Does the patient live with other family members? (1 = yes, 2 = no)....._____

If no, skip to item 101. If yes,

b. How supportive does the patient think other family members would be if he/she were asked to make changes in his/her diet? (Circle one number on the scale below.)

Not Supportive	1	2	3	4	5	Very Supportive
----------------	---	---	---	---	---	-----------------

101. Date this form completed.....___/___/___

102. Certification number of person filling out this form....._____

103. Date form entered.....___/___/___

104. Certification number of data entry person....._____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. *Do not send this form to the NCC.* Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196

Name: _____
Rev. 3 1/15/89



Modification of Diet in Renal Disease Study Nutrition History Questionnaire

This questionnaire will give the dietitian useful information about your weight, occupation, and eating habits. Your answers and comments will help the dietitian and you to design an eating pattern that includes foods you enjoy.

Please mail the completed form to your MDRD center in the self-addressed stamped envelope provided. In this way the dietitian can review the form before your next visit.

Please use a ballpoint pen - not felt tip - to complete this form.

1. Are you:
- | | |
|--|--|
| <input type="checkbox"/> Employed, full time | <input type="checkbox"/> Retired |
| <input type="checkbox"/> Employed, part time | <input type="checkbox"/> On disability |
| <input type="checkbox"/> A homemaker | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Unemployed | |

If you are not employed, skip to question 3.

2. If you are employed:
- a. Does your job require that you travel?..... Yes No
- b. If yes, does travel involve overnight stay? Yes No
- c. How often does the travel involve an overnight stay? Weekly Monthly Few/Year
3. Do any of your business or social functions include meals or refreshments?..... Yes No

If no, go on to question 4.

- b. If yes, how many times a month? _____
4. Describe other work or activities you do at home or somewhere else (for example: housework, yard work, or volunteer work).
- _____
- _____

5. Have you followed a special diet in the past? Yes No

(Questions regarding your current intake follow)

If no, go on to question 6. If yes, check which one(s).

- | | |
|---|--|
| <input type="checkbox"/> Low calorie, weight loss | <input type="checkbox"/> High fiber |
| <input type="checkbox"/> Low fat/low cholesterol | <input type="checkbox"/> Low salt |
| <input type="checkbox"/> Low protein | <input type="checkbox"/> Low potassium |
| <input type="checkbox"/> Low sugar/diabetic | <input type="checkbox"/> Other: _____ |

Name: _____
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Modification of Diet in Renal Disease Study Nutrition History Questionnaire

5. (Continued)

a. Who taught you the diet(s)?

- Doctor
- Nurse
- Relative

- Dietitian
- No one
- Other (Example Weight Watchers)

b. When and how long did you follow the diet.....

c. When and why did you stop following the diet.....

6. Are you now following (or trying to follow) any special diet? Yes No

If no, go on to question 7. If yes, check which one(s).

- Low calorie, weight loss
- Low fat/low cholesterol
- Low protein
- Low sugar/diabetic

- High fiber
- Low salt
- Low potassium
- Other: _____

a. Who recommended the special diet? (example: doctor, nurse, no one, started diet on your own) _____

b. Who taught you the diet(s)?

- Doctor
- Nurse
- Relative

- Dietitian
- No one
- Other (Example Weight Watchers)

b. When did you receive the instructions? (approximate date).....

c. When and why did you stop following the diet.....

d. Do you have difficulty following this diet? Yes No

If yes, please describe the difficulties:

7. How supportive would your spouse/significant other be if you were asked to make changes in your diet? (Circle one number on the scale below.)

Check here if this question does not apply to you

Not Supportive	1	2	3	4	5	Very Supportive
----------------	---	---	---	---	---	-----------------

Name: _____
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Modification of Diet in Renal Disease Study Nutrition History Questionnaire

8. How supportive would your other family members/people with whom you live be if you were asked to make changes in your diet? (Circle one number on the scale below.)

Check here if this question does not apply to you _____

Not Supportive	1	2	3	4	5	Very Supportive
----------------	---	---	---	---	---	-----------------

9. Who usually prepares your meals at home _____

a. For how many people? _____

10. Who usually does the grocery shopping? _____
(relationship to you)

a. Do you or whomever shops have any problems shopping for food? Yes No

If yes, please explain: _____

11. Please list the people with whom you live and indicate if they follow a special diet:

If you live alone, check here and go on to Question 12..... _____

<u>Name/Relationship</u>	<u>Type of Special Diet (if applicable)</u>

12. During the past year, has your weight:

a. Increased. By how many pounds?

b. Decreased. By how many pounds?

c. Remained about the same.

13. What do you think is the best weight for you?..... _____ pounds

a. Have you ever weighed your best weight?..... Yes No

b. If so, how old were you?

14. What is the most you have ever weighed (not counting pregnancy)?..... _____ pounds

a. How old were you?..... _____ years

Name: _____
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**Modification of Diet in Renal Disease Study
Nutrition History Questionnaire**

15. What is the least you have weighed since age 20? _____ pounds
 a. How old were you? _____ years
16. Do you lose weight easily? _____ Yes ___ No
17. Have you ever tried to gain weight? _____ Yes ___ No
18. Are you satisfied with your weight now? _____ Yes ___ No
19. Over the past year, how often have you begun a weight loss program? Number of times _____
20. How often do you use the following methods as a way to lose weight? Write one number from the scale below after each method.

1 Never	2 Rarely	3 Sometimes	4 Often	5 Always
------------	-------------	----------------	------------	-------------

- | | |
|---|--|
| <p>a. Skip meals.....</p> <p>b. Fasting.....</p> <p>c. Low carbohydrate.....</p> <p>d. Low fat.....</p> <p>e. Smaller portions.....</p> <p>f. Quick weight loss diets.....
(such as Cambridge, Herbalife)</p> <p>g. Special products.....
(such as Dexatrim, laxatives, etc.)</p> | <p>h. Reduce calories.....</p> <p>i. Diet camps/spas.....</p> <p>j. Special diet programs.....
(such as Nutri-Med, Opti-Fast, NutriSystem)</p> <p>k. High protein.....</p> <p>l. Other: _____
(please indicate what)</p> |
|---|--|
21. Have you ever had an "eating binge" (eating a large amount of food in a short period of time)? _____ Yes ___ No
 If yes, please describe _____
22. How many breakfasts do you eat in a typical week? _____
 If you do not eat breakfast, write in "0". Go on to Question 23.
- a. How many are prepared and eaten at home? _____
- b. How many are eaten out? _____
- c. Using the list in the box, please indicate where you eat breakfast out by circling the number(s) which apply:

1 = Prepared at home, but eaten out (such as lunch at work)	5 = Cafeteria
2 = Restaurant	6 = Vending machine
3 = Fast food	7 = At relative's/friend's home
4 = Take out	

Name: _____
Rev. 3 1/15/89

Modification of Diet in Renal Disease Study Nutrition History Questionnaire

23. How many lunches do you eat in a typical week?

If you do not eat lunch, write in "0". Go on to Question 24.

a. How many are prepared and eaten at home?.....

b. How many are eaten out?

c. Using the list in the box, please indicate where you eat lunch out by circling the number(s) which apply:

- | | |
|---|---------------------------------|
| 1 = Prepared at home, but eaten out (such as lunch at work) | 5 = Cafeteria |
| 2 = Restaurant | 6 = Vending machine |
| 3 = Fast food | 7 = At relative's/friend's home |
| 4 = Take out | |

24. How many dinners do you eat in a typical week?

If you do not eat dinner, write in "0". Go on to Question 25.

a. How many are prepared and eaten at home?.....

b. How many are eaten out?

c. Using the list in the box, please indicate where you eat dinner out by circling the number(s) which apply:

- | | |
|---|---------------------------------|
| 1 = Prepared at home, but eaten out (such as lunch at work) | 5 = Cafeteria |
| 2 = Restaurant | 6 = Vending machine |
| 3 = Fast food | 7 = At relative's/friend's home |
| 4 = Take out | |

25. Do you eat snacks and/or drink beverages, other than water, between meals? ___ Yes ___ No

If no, go on to Question 26.

a. How often (example: twice a day, three times a week)?

b. What time(s) of the day/night?

c. What kind of snack(s) or beverage(s)?

Name: _____
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Modification of Diet in Renal Disease Study Nutrition History Questionnaire

26. Do you ever drink alcoholic beverages?..... Yes No

If no, go on to question 27.

If yes, list the average amount of the following types of beverage and how often you have them (for example, 4 oz. of wine 6 days per week).

<u>Beverage</u>	<u>Average Amount</u>	<u>How Often</u>
Wine	_____	_____
Beer	_____	_____
Mixed drinks	_____	_____

27. Has there ever been a time when drinking (alcohol) has interfered with your work, home, or social life?..... Yes No

28. How often do you add salt to your food at the table?

- | | |
|--|--|
| <input type="checkbox"/> Never | <input type="checkbox"/> Rarely |
| <input type="checkbox"/> Occasionally | <input type="checkbox"/> Nearly always |
| <input type="checkbox"/> At every meal | |

29. How often do you add a salt substitute to your food at the table?

- | | |
|--|--|
| <input type="checkbox"/> Never | <input type="checkbox"/> Rarely |
| <input type="checkbox"/> Occasionally | <input type="checkbox"/> Nearly always |
| <input type="checkbox"/> At every meal | |

Which brand do you use? _____

30. How often is salt added to your food during cooking?

- | | |
|--|--|
| <input type="checkbox"/> Never | <input type="checkbox"/> Rarely |
| <input type="checkbox"/> Occasionally | <input type="checkbox"/> Nearly always |
| <input type="checkbox"/> At every meal | |

31. How often is a salt substitute added to your food during cooking?

- | | |
|--|--|
| <input type="checkbox"/> Never | <input type="checkbox"/> Rarely |
| <input type="checkbox"/> Occasionally | <input type="checkbox"/> Nearly always |
| <input type="checkbox"/> At every meal | |

32. How often do you feel you make healthy food choices? (Circle one number on the scale below.)

Not Often at All	1	2	3	4	5	Very Often
------------------	---	---	---	---	---	------------

33. Do you wear dentures?..... Yes No

Name: _____
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Modification of Diet in Renal Disease Study Nutrition History Questionnaire

34. Do you have any chewing problems? Yes ___ No

If yes, describe the problem (such as what you are not able to eat).

35. Do you have any swallowing problems (example: a problem taking pills)? Yes ___ No

36. Which of the following do you have at home or otherwise available for your use? Please check:

- | | |
|--|---|
| <input type="checkbox"/> Stove | <input type="checkbox"/> Refrigerator |
| <input type="checkbox"/> Freezer | <input type="checkbox"/> Food processor |
| <input type="checkbox"/> Blender | <input type="checkbox"/> Toaster oven |
| <input type="checkbox"/> Hot plate | <input type="checkbox"/> Microwave |
| <input type="checkbox"/> Food scale | <input type="checkbox"/> Body scale |
| <input type="checkbox"/> Personal computer | <input type="checkbox"/> Calculator |
| <input type="checkbox"/> VCR | |

37. Are you now taking any vitamin, mineral, or other supplements (such as: multi-vitamin, One-A-Day, fish oil capsules, vitamin E, medicinal herbs, etc.)? Yes ___ No

If no, skip to item 38.

If yes, please list the supplement(s), how much you take, how often, and who recommended the supplement(s). (Provide labels if available.)

<u>Supplement</u>	<u>Amount</u>	<u>How Often</u>	<u>Who Recommended It</u>
<i>Example:</i> Vitamin C	250 mg	one per day	friend
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

38. Are there any foods you don't eat because you are allergic to or can't tolerate them? Yes ___ No

If yes, please list the foods:

Name: _____
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**Modification of Diet in Renal Disease Study
Nutrition History Questionnaire**

39. Are there any foods you don't eat because you just don't like them? Yes No

If yes, please list the foods:

40. Are there any foods you don't eat because of religious or other reasons? Yes No

If yes, please list the foods:

41. What are some of your favorite foods?

42. Did you fill out this form yourself? Yes No

If no, who helped you? _____

Thank you.

Modification of Diet in Renal Disease Study
Special Food Products Order Form

Purpose: To provide a method for the patient to order Special Food Products on a regular basis and for the dietitian to record what food was actually distributed to the patient.

To be completed by the dietitian beginning at Follow-Up Visit 1 or 1A when the patient receives a Special Food Products introductory package for the first time and then at each visit when food products are distributed to the patient. The dietitian completes the AMOUNT columns to record which foods were DISTRIBUTED to the patient.

Pages two and three of the form may be given to the patient at one visit to be taken home, completed, and returned at the following visit. Or the patient may be asked at each visit what special food products he would like and the columns completed at that time.

Only the amount of food that is actually distributed to the patient is to be recorded on the form. If the patient orders a food product which is not in stock or the number of packages actually distributed is different than what the patient ordered, the form should be changed accordingly.

Please note that under Items 9, 21, 22, 23, 24, 41, 42, and 43, the TOTAL NUMBER of packages of pasta, baking mix, cookies, gelled dessert mix, GO, Carnation Instant Breakfast and Buitoni pasta is to be totalled and entered in the AMOUNT COLUMN.

Instructions:

- a) At Follow-Up Visit 1 or 1A, patients receive an introductory Special Food Products package. The samples provided in the introductory package are at the discretion of the dietitian.
- b) The dietitian completes the Amount columns of pages 2 and 3 to record which foods were distributed at this visit.
- c) The patient may also receive a new copy of pages 2 and 3 of this form. The patient is encouraged to try the Special Food Products at home and return the form at his next visit. He is asked to return the form with the Amount column of pages 2 and 3 completed indicating which food products and what amounts he would like for the next month.
- d) The dietitian distributes the Special Food Products that the patient has requested and completes the Amount columns of pages 2 and 3.

- e) If the amount of food actually given to the patient is different than the amount ordered by the patient, the form should be changed accordingly. Thus the form will record the foods ACTUALLY DISTRIBUTED to the patient.
- f) The patient may choose not to take the form home, but complete it at the visit. Or the dietitian may just ask the patient which foods he would like. Again, the Amount columns are completed for the amount of foods actually distributed.
- g) Please note that for certain products it is not necessary to enter a specific flavor or type in the Amount column.

For the following item numbers, enter only the TOTAL in the Amount column:

- Item 19 - Other Low Protein Pastas
- Item 20 - Other Baking Mixes
- Item 21 - Other Cookies
- Item 39 - "Go" Mix Drink
- Item 40 - Carnation Instant Breakfast
- Item 41 - Buitoni Pasta

- h) Items 42-50 - As new products become available, they will be recorded in these spaces with codes assigned by the NOC.

Blanks on this form will be treated as zeros. Thus no "missing" data.

For DCC Use Only
Rev. 2 2/15/91

E ___
V ___
T ___

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Page 1 of 3



Modification of Diet in Renal Disease Study Special Food Products Order Form

Purpose: To provide a method for the patient to order Special Food Products on a regular basis and for the dietitian to record what food was actually distributed to the patient.

To be completed by the dietitian beginning at Follow-Up Visit 1 or 1A when the patient receives a Special Food Products introductory package for the first time and then at each visit when food products are distributed to the patient. The dietitian completes the AMOUNT columns to record which foods were distributed to the patient.

Page 2 and 3 of the form may be given to the patient at one visit to be taken home, completed, and returned at the following visit. Or the patient may be asked at each visit what special food products he would like.

Only the amount of food that is actually distributed to the patient is to be recorded on the form. If the patient orders a food product which is not in stock or the number of packages actually distributed is different than what the patient ordered, the form should be changed accordingly.

Please note that under items 19, 20, 21, 22, 39, 40, and 41, the total number of packages of pasta, baking mix, cookies, etc., is to be totaled and recorded in the amount column.

(Note: This form should be entered into Datalex.)

FORM # 79

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. a. Date of visit at which the food is given to the patient / /
b. Visit Type E
c. Visit Number.....

101. Date this form completed..... / /
102. Certification number of person filling out this form
103. Date form entered..... / /
104. Certification number of data entry person

Retain this form for your files.

PWO 1817

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**Modification of Diet in Renal Disease Study
 Special Food Products Order Form**

Name: _____

Low Protein Products

Please mark the amounts of the items you would like and give this order blank to your dietitian.

Product	Amount	Product	Amount
5. Alterna Lo Pro Dairy Drink Mix (pkg)	_____	19. Other Low Protein Pasta	_____
6. Unimix - Kingsmill Baking Mix (pkg)	_____	<i>(Total Pastas Listed Below)</i>	
7. Lo Pro Rice Starch Bread (loaf)	_____	Aproten Anellini	_____
8. Wel-Plan Cream-Filled Vanilla Wafers (box)	_____	Aproten Ditalini	_____
9. Prono Gelled Dessert Mix (pkg)	_____	Aproten Fusilli	_____
10. Wel-Plan Macaroni (box)	_____	Aproten Rigatini	_____
11. Wel-Plan Short Cut Spaghetti (box)	_____	Aproten Spaghetti	_____
12. Wel-Plan Spaghetti Rings (box)	_____	_____ ..	_____
13. Aproten Tagliatelle Pasta (box)	_____	<i>List Type</i>	
14. Aproten Rusks (box)	_____	20. Other Baking Mixes	_____
15. Med-Diet Chocolate Chip Cookies (package)	_____	<i>(Total Mixes Listed Below)</i>	
16. Med-Diet Spice Cookies (package)	_____	Wel-Plan Baking Mix	_____
17. R & D Ratatouille (package)	_____	dp Baking Mix	_____
18. Other Low Protein Bread	_____	Other Baking Mix	_____
_____		21. Other Cookies	_____
<i>List Type</i>		<i>(Total Cookies Listed Below)</i>	
		Med-Diet Vanilla Creme Wafers (package)	_____
		Wel-Plan Sweet Cookie (package)	_____
		Wel-Plan Chocolate Filled Wafer (package)	_____
		Wel-Plan Chocolate Cookies (package)	_____
		_____ ..	_____
		<i>List Type</i>	

2.305.4

**Modification of Diet in Renal Disease Study
 Special Food Products Order Form**

Product	Amount	Product	Amount
22. Other LoPro Gelled Dessert Mix.....	_____	40. Carnation Instant Breakfast.....	_____
<i>List Type</i>	_____	Reg. or Unsweetened (Circle Type)	_____
		(Total Flavors Listed Below)	
23. Wel-Plan LoPro Crackers (bx).	_____	<i>List Flavor</i>	_____
24. dp Wheat Starch (package)....	_____	<i>List Flavor</i>	_____
25. Low Pro Rice Starch (pkg)	_____	41. Buitoni Pasta.....	_____
26. Kingsmill Cake and Cookie Base (package)	_____	(Total Types Listed Below)	
27. R & D Creamy Lemon Herb Sauce (package).....	_____	<i>List Type</i>	_____
28. R & D Garlic Herb Sauce (package).....	_____	<i>List Type</i>	_____
29. R & D Tomato Sauce (pkg).....	_____	<i>List Type</i>	_____
30. Polycose Powder OR Liquid (Circle Type)	_____	Other Products	Code #
31. Med Diet Cheddar Cheese Sauce (pkg).....	_____	42. _____	_____
32. Apple Chips (package).....	_____	<i>List Type</i>	_____
33. Low Protein Rice (box).....	_____	43. _____	_____
34. Low Protein Porridge (box)....	_____	<i>List Type</i>	_____
35. Baxter Beef Stew (package) ..	_____	44. _____	_____
36. Baxter Corn Chowder (pkg) ...	_____	<i>List Type</i>	_____
37. Baxter Pasta Alfredo (pkg).....	_____	45. _____	_____
38. Baxter Oriental Rice (pkg).....	_____	<i>List Type</i>	_____
39. "GO" Milk Drink (package).....	_____	46. _____	_____
(Total Flavors Listed Below)		<i>List Type</i>	_____
<i>List Flavor</i>	_____	47. _____	_____
		<i>List Type</i>	_____
<i>List Flavor</i>	_____	48. _____	_____
		<i>List Type</i>	_____
		49. _____	_____
		<i>List Type</i>	_____
		50. _____	_____
		<i>List Type</i>	_____

[]

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E ___
V ___
T ___

Form # 80
Page 1 of 5

MDRD

Modification of Diet in Renal Disease Study Low Protein Entrees Acceptability

Purpose: To assess the acceptability and convenience of Baxter Low Protein Entrees being introduced to the study. To determine the use and acceptability of other low protein food products. To investigate other types of food products that would be acceptable to MDRD patients.

To be given to the patient when he/she receives his/her first sample package of Baxter Low Protein Entrees. The patient is asked to taste each of the four entrees, complete the form and return the form at his/her next visit.

Procedure: The form is to be explained to the patient by the designated reviewer and reviewed for completeness when returned by the patient.

FORM # 8 0

1. Patient Identification Number..... _____

2. Patient Name Code..... _____

103. Date form entered..... ____/____/____

104. Certification number of data entry person _____

Send the original to the MDRD Study Nutrition Coordinating Center. Please use MDRD Study mailing labels.

**Modification of Diet in Renal Disease Study
 Low Protein Entrees Acceptability**

**Baxter Low Protein Entrees
 Taste Test**

Thank you for taking the time to answer this Questionnaire

Please fill in the blanks or circle the most appropriate response.

CONVENIENCE AND HANDLING

1. Please write down the date you received these products. _____/_____/_____

2. What was the condition of the carton when you received it?

Poor Condition 1 2 3 4 5 Excellent Condition

3. Please indicate with an "X" the meal at which you ate the entree. (Please circle the "X" if the entree was not prepared at home.)

	Weekday			Weekend		
	Breakfast	Lunch	Dinner	Breakfast	Lunch	Dinner
Country Stew						
Corn Chowder						
Pasta Alfredo						
Vegetable Stirfry						

4. If you prepared any of these meals outside your home, list where you most often prepared them.....

- 1 - Work
- 2 - Travel
- 3 - Home of friend or relative
- 4 - Other

TASTE AND APPEARANCE

Please rate and provide any comments on the taste, texture, and appearance of the four different meals. Circle the number below which most accurately reflects your rating.

5. **COUNTRY STEW WITH BEEF** - If you did not taste this entree, skip to the next entree.

a. **Taste**

Poor taste 1 2 3 4 5 Very delicious

b. **Texture**

Unacceptable 1 2 3 4 5 Acceptable

**Modification of Diet in Renal Disease Study
Low Protein Entrees Acceptability**

c. Appearance

Unappetizing 1 2 3 4 5 Very appetizing

d. Comments (up to 60 characters):

6. HEARTY CORN CHOWDER - If you did not taste this entree, skip to the next entree.

a. Taste

Poor taste 1 2 3 4 5 Very delicious

b. Texture

Unacceptable 1 2 3 4 5 Acceptable

c. Appearance

Unappetizing 1 2 3 4 5 Very appetizing

d. Comments (up to 60 characters):

7. PASTA ALFREDO WITH BACON - If you did not taste this entree, skip to the next entree.

a. Taste

Poor taste 1 2 3 4 5 Very delicious

b. Texture

Unacceptable 1 2 3 4 5 Acceptable

c. Appearance

Unappetizing 1 2 3 4 5 Very appetizing

d. Comments (up to 60 characters):

**Modification of Diet in Renal Disease Study
 Low Protein Entrees Acceptability**

8. **VEGETABLE STIR FRY WITH PORK** - If you did not taste this entree, skip to the next entree.

a. **Taste**

Poor taste 1 2 3 4 5 Very delicious

b. **Texture**

Unacceptable 1 2 3 4 5 Acceptable

c. **Appearance**

Unappetizing 1 2 3 4 5 Very appetizing

d. **Comments** (up to 60 characters):

9. For products which were consumed away from home, did you experience any difficulty?

a. **Transporting** 1 = Yes 2 = No....._____

b. **Storage** 1 = Yes 2 = No....._____

c. **Heating** 1 = Yes 2 = No....._____

10. Did these entrees make it difficult to meet your MDRD protein goal?

Difficult 1 2 3 4 5 Easier

11. Overall, based on convenience and taste, how would you rate these entrees?

Poor 1 2 3 4 5 Excellent

12. Do you currently use food products supplied by the MDRD Study? (1 = Yes, 2 = No)....._____

13. If these products were available through the MDRD Study would you order them through your dietitian? (1 = Yes, 2 = No)....._____

14. If yes, which products would you order and how many entrees would you order per month?

Entrees	Number you would order per month
a. Country Stew.....	_____
b. Hearty Corn Chowder.....	_____
c. Pasta Alfredo.....	_____
d. Vegetable Stirfry.....	_____

**Modification of Diet in Renal Disease Study
Low Protein Entrees Acceptability**

15. If these products were available after the MDRD Study is over, would you want to buy these products? (1 = Yes, 2 = No)....._____

16. If yes, how much would you be willing to pay for each entree:

a. Country Stew\$ _____ . _____

b. Hearty Corn Chowder.....\$ _____ . _____

c. Pasta Alfredo.....\$ _____ . _____

d. Vegetable Stirfry.....\$ _____ . _____

17. What other food products would you like to see developed for your use? (Up to 60 characters)

THANK YOU for your valuable comments!