

**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.

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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.
<b>HYPERTENSION</b>	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.
<b>CANCER</b>	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.
<b>HEART</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.
<b>LUNG</b>	Enter a 1 if the patient demonstrates severe chronic lung disease causing cor pulmonale or requiring steroid therapy.
<b>LIVER</b>	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.

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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

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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.

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**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 .....

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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  $\geq 10$  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 .....