

**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
