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.

QUESTION #	INSTRUCTIONS
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.- 1., 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.

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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.

		Equivalency
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.

MDRD

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 # 0 8

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?

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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 l, 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 ..... ___

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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)....___

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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
    2 = Transplant
    3 = Study team preference
    4 = Other (20 characters maximum) (_____)
    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
