

**Modification of Diet in Renal Disease Study
STUDY A AND B RANDOMIZATION FORM**

This form will be completed at the time of the randomization phone call, by DCC personnel. It will then be entered by them, sent to the appropriate Clinical Center, and serve as the official randomization record.

QUESTION # INSTRUCTIONS

- 7. Enter the patient's average dietary protein intake in grams per kilogram per day. If the patient is Study A, the value must be ≥ 0.9 . The average should be the 3 most recent 24-hour urines.
- 8. Enter the final Baseline GFR value from Baseline Visit 3.
- 9. Enter the appropriate code for the patient's study and GFR stratification.

<u>STUDY</u>	<u>GFR</u>	<u>CODE</u>
A	25-55 ml/min/1.73m ²	1
B	13-24 ml/min/1.73m ²	2

- 11. Enter the slope from the progression program at the time of screening the patient for the Baseline Period.
- 12. Enter the assignment number from the randomization schedule.
- 13. After looking in the randomization list, enter the code associated with the diet that the patient should be assigned to.
- 14. Blood Pressure assignment

1 = Moderate MAP goal.....	18-60,	MAP \leq 107
	≥ 61 ,	MAP \leq 113
2 = Low MAP goal.....	18-60,	MAP \leq 92
	≥ 61 ,	MAP \leq 98

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

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MDRD

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

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**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

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