

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.

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

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V ___
T ___

Form # 09
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**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