

**Modification of Diet in Renal Disease Study
ACTION ITEM RESPONSE FORM**

This form is to be completed every month that a patient reaches an action item. It is to be entered into Datalex Entrypoint 90. Comment carefully with key words, doses, repeats etc...

If the response to an action item is to follow the protocol exactly, you do not need to complete the text portion of the question.

Do not worry about having question 15 on Form 5 correspond with the number of action item Form 23's that are completed.

This then brings up the question of how to identify the visit type and number on the Form 23 for any given action item. Since you may not have all the central lab data from a particular visit (i.e. Follow-up #3), you will not be able to complete the entire Form 23 (or all the Form 23's needed) until after the F-3.0. You may choose to complete it at the patients next F-4.0 with the appropriate visit number of F-3.0 which is what the action item flow sheet would also reflect.

For DCC Use Only
Rev. 3 3/27/90

E ___
V ___
T ___



Modification of Diet in Renal Disease Study Action Item Response Form

This form is to be completed once for each visit when at least one action item has occurred. It should not be completed until complete documentation of the occurrence of action items is available and a course of treatment has been determined.

FORM # 23

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center
4. a. Date of visit..... / /
- b. Visit type.....
- c. Visit number.....

The following is a coding list for the questions asked below.

- | | |
|---------------------------------------|--|
| 1 = GFR (Study A Only) | 17 = Persistent Four Month Mean UNA Out-of-Range |
| 2 = Weight Loss | 18 = Low Serum Phosphorus |
| 3 = Weight Gain | 19 = Low Serum Calcium |
| 4 = Overweight Diabetic | 20 = High Serum Calcium |
| 5 = High Blood Pressure | 21 = High Serum Potassium |
| 6 = Persistent High Blood Pressure | 22 = Low Serum Bicarbonate |
| 7 = Low Blood Pressure Symptoms | 23 = Low Serum Magnesium |
| 8 = Persistent Low Blood Pressure | 24 = Low Serum Iron |
| 9 = Declining Serum Albumin | 25 = High Serum Cholesterol |
| 10 = Low Serum Albumin | 26 = High Serum LDL Cholesterol |
| 11 = Declining Serum Transferrin | 27 = High Serum Triglycerides |
| 12 = High Serum Phosphorus | 28 = Low Vitamin A |
| 13 = Very High Serum Phosphorus | 29 = 4 Month Aminogram (14b) |
| 14 = Absent Alloisoleucine | 30 = Persistent Aminogram (14c) |
| 15 = Monthly UNA Out-of-Range | |
| 16 = Four Month Mean UNA Out-of-Range | |

Below list all action items which occurred, and the steps being taken to resolve them. Please be specific.

5. a. Action item code number
- b. Was this action handled according to the protocol? (1 = yes, 2 = no)
- c1. Steps: _____
- c2. _____
- c3. _____

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6. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
7. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
8. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
9. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____
10. a. Action item code number _____
b. Was this action handled according to the protocol? (1 = yes, 2 = no) _____
c1. Steps: _____
c2. _____
c3. _____

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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
