

**Modification of Diet in Renal Disease Study  
MONTHLY EXAMINATION FORM**

This form is to be completed by the study coordinator, physician and dietitian at each monthly visit after Baseline 0. In addition, Refer to Page 10 for a schedule of forms completion. Even if the visit is missed, it is very important to complete, enter and transmit this form in a timely fashion.

- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u>  |
|-------------------|--|
| 4.                | <p>a. Enter the actual date of the visit if the patient kept appointment. If the visit was missed, fill in the target date from the appointment schedule generated by the DCC and complete Form 05 as indicated. ONLY FOLLOW-UP VISITS CAN BE "MISSED".</p> <p>b. Also, use visit type = K for all Study C post stop point visits.</p>   |
| 5.                | <p>a. A visit is considered missed if the patient is not able to be scheduled within the window specified in the Protocol. Missed visits in follow-up should not be made up. Move on to hold the next monthly visit in its window.</p> <p>b. Keep the reasons to these general categories.</p>   |
| 6a.               | This question was added 2/91 to address long term illness.   |
| 7.                | If the patient does not smoke, enter 00.00.  |
| 9a.               | Enter the patient's weight at the visit rounded to the nearest tenth of a kilogram. The Datalex range is 40-130. It should be measured and recorded twice. The dietitian does <u>not</u> need to be the person to complete this item.  |
| 9b.               | The patient's weight status should be recorded at each visit to assist in determining whether or not the patient has reached a weight action item. (Undesired weight loss of more than 5% of standard body weight from the B3 visit to a weight of 75-95% of standard body weight in a patient without edema, or loss of weight to less than 75% standard body weight.) Refer to Protocol. |
| 9c/d.             | This question relates to the change in weight action items in January 1991.  |
| 10.               | Enter the code which best describes the amount of edema.   |
| 11.-13.           | At each patient visit, medications and dosages should be carefully reviewed. Changes should be recorded in the appropriate section. New drugs prescribed at a visit are recorded on that monthly visit form. 'Since the last monthly patient visit' means after the last visit, up to and including this visit.  |

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The code number from the attached list, the dosage, IN THE CORRECT UNITS, and the number of times/day should be listed for each drug the patient is taking presently.

Drug doses - If patient receives a dose which includes decimals (12.5 2 times a day) you must enter the decimal point in one of the dashes provided. Similar to completing Forms 24 and 25. If a dose is truly missing, enter 999999.

The following codes should be used as "times per day" if a drug is taken at unusual frequencies:

- 85 = once every 10 days
- 86 = once every other week
- 87 = four times per month
- 88 = once every 5 days
- 89 = two weeks/month
- 90 = 5 times per week
- 91 = every other day
- 92 = once a week
- 93 = 3/week
- 94 = 3 weeks/month
- 95 = once a month
- 96 = twice a week
- 97 = once every 3 weeks
- 98 = 4 times per week
- 99 = PRN

- 14. During baseline this should always be 2=No.
- 15. Any action items that the center is aware of at the time the form is completed should be recorded here. If yes, there will be at least one Form 23 completed. Central action item measurements will be reported to the Clinical Center when the data becomes available. Refer to the Protocol for a review of action items. Remember, there are no action items during Baseline.

2.76.1

For DCC Use Only  
Rev. 4 2/28/91

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### Modification of Diet in Renal Disease Study Monthly Examination Form

This form is to be completed by the study team at the time of each scheduled monthly clinic visit.

FORM # ..... 05

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center.....
- 4. a. Date of this clinic visit (Enter target date from appointment schedule if missed)..... / /
- b. Visit Type (B = Baseline, F = Follow-up).....
- c. Visit Number.....
 

0.0 = Baseline Visit 0	1.0 = Follow-up Visit 1
1.0 = Baseline Visit 1	2.0 = Follow-up Visit 2
2.0 = Baseline Visit 2	3.0 = Follow-up Visit 3
3.0 = Baseline Visit 3	4.0 = Follow-up Visit 4 (etc.)

5. a. Was this visit missed? (outside window, not held) (1 = yes, 2 = no) .....

If yes,

- b. Reason visit was missed.....
 

1 = Short-term illness	8 = Forgot
2 = Long-term illness	9 = Patient refused
3 = Hospitalization due to short-term illness	10 = Weather
4 = Hospitalization due to long-term illness	11 = Moved
5 = Personal family business	12 = Could not contact
6 = Work related business	13 = Other (20 characters maximum)
7 = Vacation	(.....)
	14 = Unknown

If the visit was missed, skip to item 101.

If the visit was missed due to reason 3 or 4, complete the Unscheduled Attention Form (Form #10).

- 6. Has the patient had any illnesses or health concerns in the past month for which the patient was seen by a physician? (1 = yes, 2 = no) If hospitalized, Complete Unscheduled Attention Form (Form #10).....
- a. At the time of this visit does the patient have a long term illness? (1 = yes, 2 = no).....
- 7. How many packs per day does the patient smoke?.....

277



**Modification of Diet in Renal Disease Study  
Monthly Examination Form**

13. Since the last monthly patient visit, did any drug doses change? (1 = yes, 2 = no).....

If yes,

	Code Number	Dosage	Times/Day
a.	_____	_____	_____
b.	_____	_____	_____
c.	_____	_____	_____
d.	_____	_____	_____
e.	_____	_____	_____
f.	_____	_____	_____

14. Did symptoms related to low blood pressure occur 2 or more days since the last visit?  
(action item) (1 = yes, 2 = no).....

15. Were any action items identified locally since the last monthly visit? (1 = yes, 2 = no) .....

If yes, Complete Action Item Response Form (Form # 23)

16. How much time has the dietitian spent in patient care related activities preparing for and at  
this visit? (To be provided by the dietitian.)  
(hh:mm) .....

17. How much time has the physician spent in patient care related activities preparing for and  
at this visit? (To be provided by the physician.)  
(hh:mm) .....

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 .....