Modification of Diet in Renal Disease Study
GFR DETERMINATION WORKSHEET FORM

This form should be completed by the GFR nurse/technician or other GFR certified personnel. Be sure that times are recorded in 24-hour clock. Include a copy of this form with the samples being shipped to the Central GFR Lab. Complete, enter and transmit the form in the usual manner. Complete this form for all required GFR's, whether they were done or not.

QUESTION #	INSTRUCTIONS
4 b.c.	Visit type and number for routine GFR's inside their windows must be the scheduled protocol visit numbers regardless of which visit the GFR procedure was actually done. (i.e., B0, B3, F2, F4, F8, F12, etc...) The GFR must be done in its ± 30 day time schedule from the target date. If not, it is an unrequired GFR and 4d would be labelled as 4 = not required by protocol. Only 1 GFR form should be transmitted for each protocol GFR. If the B-3.0 GFR CV is not within range, but otherwise valid, the GFR can be "repeated" by holding another GFR visit within the allowable Baseline period and labelling it as visit number 3.9.
4 d.	For choices 3 and 4 in item 4d enter the visit type and number of the most recent scheduled monthly visit prior to this GFR test (i.e. If item 4d = 3 then use the most recent visit held). For choice 2, visit type = P and visit number = 1.0 (unless it is a Study C patient who has reached a second stop point (VISN = 2.0). P = Soon after stop point. This should be used to identify the GFR done after a stop point is reached. Following this, visits at 4 month intervals will be labelled A. If the GFR was repeated for an action item, but was not repeated until the next regularly scheduled GFR (4 months later), Q04D should reflect a code of 1.
5-6.	Pregnancy testing is required on all menstruating (able to become pregnant) females. If the pregnancy test was not completed, the GFR must be rescheduled. If it is found to be positive, notify the physician. DO NOT DO GFR.
10 b.	Check to see if the patient has had any non-steroidal anti-inflammatory agents (including aspirin), cimetidine, ranitidine, trimethoprim/sulfamethoxazole or trimethoprim. Be careful, this question is worded backwards from the way it is asked on Form 17.
11.	Answer yes only if an "acceptable" GFR test was performed that will result in a GFR being calculated. Two period GFR's are not considered acceptable except for the B-0.0 GFR.

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QUESTION #	INSTRUCTIONS
16.	Complete urine flow rate worksheet to determine if patient is hydrated enough to continue test.
17.- 21.	Time interval between Time #0, #1, #2, #3, and #4 must be a minimum of 30 minutes. See the manual of operations for a complete discussion of GFR Methods. ALL TIMES SHOULD BE RECORDED AS 24-HOUR CLOCK TIMES.
22.	As specified in the Manual of Operations, if during any period either 1) the urine collection is incomplete or 2) the urine collection is contaminated with feces, the results of that period cannot be calculated. In this case, a fifth period should be collected. For split sample QC, after you have received the orignal GFR report and know it was analyzable, then you can submit Form 22 and the QC Form 16. The QC Id and namecode, a "fake" date of GFR (3-14 days after the original) and the rest of the form should be copied from the original except for questions 101-103.

For DCC Use Only
Rev. 4 10/4/90

E ___
V ___
T ___

MDRD

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This form is to be completed for ALL required GFR tests.

FORM # 1 6

1. Patient Identification Number ..... ___ ___ ___ ___ ___ ___
2. Patient Name Code ..... ___ ___ ___ ___
3. Clinical Center ..... ___ ___
4. a. Date of GFR test ..... ___ ___/ ___ ___/ ___ ___

   b. Visit Type ..... ___

   c. Visit Number ..... ___ ___ . ___

   d. Type of GFR ..... ___
      1 = Regularly scheduled GFR
      2 = 2 weeks after stop point
      3 = Repeat within one month of GFR action item
      4 = Not required by Protocol

Pregnancy Testing

5. Is the patient able to become pregnant? (1 = yes, 2 = no) ..... ___

   If no, skip to Item 7.

6. a. Was the pregnancy test performed? (1 = yes, 2 = no) ..... ___

   If no, skip to Item 7.

   b. Has a copy of the written report of results been obtained? (1 = yes, 2 = no) ..... ___

   c. Date of pregnancy test ..... ___ ___/ ___ ___/ ___ ___

   d. Result (1 = positive, 2 = negative) ..... ___

   If positive, do not perform the GFR. Notify the physician.

7. Did the patient have a short-term illness as defined in the protocol on the day of the GFR? (1 = yes, 2 = no) ..... ___

8. Have any new serious medical conditions developed (as defined in the protocol)? (1 = yes, 2 = no) ..... ___

   If yes, notify the Principal Investigator, who will determine if the study should be performed or rescheduled. Complete the Unscheduled Attention Form if appropriate.

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9. Has the patient been fasting for at least 8 hours? (1 = yes, 2 = no)..... ___

10. a. Has the patient had any radionuclide diagnostic tests OTHER than ones done with 99-Technetium (^{99}Tc as in ^{99}Tc-DTPA, renal flow scan) within the past 30 days? (1 = yes, 2 = no)..... ___

If yes, DO NOT DO GFR. Reschedule test for a date at least 30 days from date of radionuclide test.

b. Has the patient taken any NSAIDS (Motrin, Advil, etc..See MOP) in the past 48 hours? (1 = yes, 2 = no)..... ___

If yes, DO NOT DO GFR. Discontinue medications and reschedule GFR 48 hours after last medications taken.

NOTE: Usual diuretics and antihypertensive agents should not be withheld prior to the GFR test.

If the answer to item 7 is "yes" or 9 is "no" or 10 a or b is "yes", the study should not be performed on this date. Try to reschedule within window.

11. Was GFR test performed? (1 = yes, 2 = no)..... ___

If GFR was not done, skip to item 25.

12. Is ^{125}I-sodium iothalamate (Glofil) being used? (1 = yes, 2 = no)..... ___

13. a. Did the patient take 5 ml/kg water load at home? (1 = yes, 2 = no)..... ___

b. Did the patient receive 10 ml/kg water load during first 60 to 90 minutes at the clinic? (1 = yes, 2 = no)..... ___

c. Did the patient receive an additional 200-400 ml of water every hour after the first hour during the visit? (1 = yes, 2 = no)..... ___

d. If the patient did not receive 200-400 ml water load every hour how much was received? (ml/hour)..... ___ ___ ___ ___

Record Times in military time, i.e. record 1:00 p.m. as 13:00.

14. a. Has SSKI been given? (1 = yes, 2 = no)..... ___

b. If yes, time (24-hour clock)..... ___ ___ : ___ ___

15. a. Has **Background Blood** been drawn? (1 = yes, 2 = no)..... ___

Have patient void. Collect urine, labelling it **Background Urine**.

b. Time **Background Urine** collected (24-hour clock)..... ___ ___ : ___ ___

c. Volume of Background Urine (cc)..... ___ ___ ___

16. Inject Glofil subcutaneously.
Time of injection (hrs:min)..... ___ ___ : ___ ___

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Wait at least 60 minutes but not more than 90 minutes to collect discard urine. Complete urine flow rate worksheet (FORM #16w) to determine if patient is hydrated enough to continue. Complete item 17 with totals from worksheet.

17. a. Time #0 (hours:minutes)..... ___ ___ : ___ ___

    Have patient void. Collect urine, labelling it **Discard Urine.**

    b. Volume of **Discard Urine** (cc)..... ___ ___ ___

    c. Urine Flow Rate at Time #0 (ml/min)..... ___ ___ . ___

    d. Has **Blood #0** been drawn? (1 = yes, 2 = no)..... ___

18. a. Time #1 (hours:minutes)..... ___ ___ : ___ ___

    b. Volume of **Urine #1** (cc)..... ___ ___ ___

    c. Has **Blood #1** been drawn? (1 = yes, 2 = no)..... ___

19. a. Time #2 (hours:minutes)..... ___ ___ : ___ ___

    b. Volume of **Urine #2** (cc)..... ___ ___ ___

    c. Has **Blood #2** been drawn? (1 = yes, 2 = no)..... ___

20. a. Time #3 (hours:minutes)..... ___ ___ : ___ ___

    b. Volume of **Urine #3** (cc)..... ___ ___ ___

    c. Has **Blood #3** been drawn? (1 = yes, 2 = no)..... ___

21. a. Time #4 (hours:minutes)..... ___ ___ : ___ ___

    b. Volume of **Urine #4** (cc)..... ___ ___ ___

    c. Has **Blood #4** been drawn? (1 = yes, 2 = no)..... ___

22. Optional 5th Period (To be done when a problem occurs during one of the first four periods)

    a. Time #5 (hours:minutes)..... ___ ___ : ___ ___

    b. Volume of **Urine #5** (cc)..... ___ ___ ___

    c. Has **Blood #5** been drawn? (1 = yes, 2 = no)..... ___

    Separate the blood by centrifugation and place the serum in the corresponding vials. Aliquot urine into appropriate vials as well.

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23. Which of the following samples have been sent? (1 = yes, 2 = no)

a.	Background Serum.....___	h.	Background Urine.....___
b.	Serum #0.....___	i.	Urine #1.....___
c.	Serum #1.....___	j.	Urine #2.....___
d.	Serum #2.....___	k.	Urine #3.....___
e.	Serum #3.....___	l.	Urine #4.....___
f.	Serum #4.....___	m.	Urine #5.....___
g.	Serum #5.....___		

24. Were there any problems obtaining blood samples or do you suspect any urine collection to be incomplete? (1 = yes, 2 = no).....___

Comments: _____

_____

_____

25. a. Have samples been sent to central GFR lab? (1 = yes, 2 = no).....___

b. Date samples sent to the Central GFR Laboratory..... ___ ___/ ___ ___/ ___ ___

101. Certification number of MDRD Technician..... ___ ___ ___ ___ ___

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 GFR Central Lab. Please use MDRD Study mailing labels:

MDRD GFR Laboratory
Desk A101
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5042
