MDRD Close Out Manual of Operations

Appendix 12 to the Study Coordinators' Chapter
MDRD Manual of Operations: Volume I

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Appendices

Color Codes for Folders

Grey:	Close Out (Final Follow-Up) Visit for Randomized (Pre-Stop Point) Patients
White:	Close Out Visit for Post Stop Point Patients
Black:	Personal Results for Randomized (Pre Stop Point) Patients
Dark Blue:	Study Results for Randomized (Pre Stop Point) Patients
Light Blue:	Study Results (with Personal Results) for Post Stop Point Patients

MDRD Close Out Manual

1. Introduction

The purpose of the MDRD Close Out Manual of Operations is to provide operational details on the MDRD close out process. There are three groups of patients to be closed out: 1) randomized patients currently being followed as part of Study A, B or C; 2) randomized patients who reached a stop point before their close out visit; and 3) the Study F patients. In this manual, Sections 3 to 5 refer to the randomized patients, Section 6 refers to post stop point patients and Section 7 refers to Study F patients.

2. Preparing for Close Out

2.1 Staff Training Plans

The Study Coordinators, Key Entry personnel, Dietitians, and MDRD Technicians were trained for Close Out at the last annual meeting of MDRD Phase III, September 30 to October 2, 1992. The material covered in this manual was discussed at training, and a second draft of the manual was distributed.

2.2 Informed Consent for Close Out Sample Storage Bank

The example informed consent forms for the Close Out sample storage bank were distributed on September 23, 1992. These were to be submitted to each center's IRB for approval prior to the start of Close Out.

2.3 Patient Preparation

At each patient's visit before their final Follow-Up Visit, the patient will receive the "What's Next?" handout and the "About the Nutrition Program Survey" handout. These handouts are included in Appendix 1, pages 1 and 2.

At that visit, the Clinical Center staff will also confirm the correct addresses and phone numbers for each patient and the names and addresses of the patients' referring physicians. Also, confirm the previously collected name and current address of the patient's friend or family member who will know how to reach the patient if needed in the future.

Study F patient addresses should also be confirmed for mailing the letters of appreciation and Study F evaluation forms for those who do not attend visits.

The Clinical Center staff members must also obtain the names and phone number of the dialysis providers who serve patients on dialysis. (Letters will later be sent to those dialysis providers, detailing the data we will expect from them as part of Phase V, Study 2.)

2.4 Preparing Letters to Referring Physicians

Prior to each patient's Close Out Visit, a customized thank you letter to each patient's referring physician must be prepared, so the patient's own copy of the letter to his or her referring physician can be placed in his or her final follow-up visit folder prior to his or her arrival at Close Out.

2.5 Preparing the Certificate

General certificates of appreciation from NIH will be provided soon. Prior to each patient's Close Out Visit, the NCC or the clinical center staff will customize these certificates by adding the patient's name, done either in calligraphy or in an attractive font on the laser printer. Each patient's certificate should be placed in his or her final follow-up visit folder prior to his or her arrival at Close Out.

2.6 Drafting the Major Results Paper

During Close Out, the MDRD Executive Committee will prepare a draft of the Phase III Major Results Paper. The draft will use the most recently available data. This draft will be reviewed by the External Monitoring Committee at their meeting early in 1993.

3. Final Follow Up (Close Out) Visits for Randomized Patients in Studies A, B, and C

3.1 Visit Summary and Visit Windows

Each patient will continue monthly visits on his or her usual MDRD treatment regimens and will be encouraged to keep complying until the day of his or her Close Out Visit. Patients who have a GFR visit scheduled in September or November have their Close Out Visit targeted for their November visit date. Patients who have a GFR visit scheduled in

October or December have their Close Out Visit targeted for their December visit date. (The patients who have close out visits in December will have regular monthly visits in November.)

The Close Out Visits are scheduled to be held between November 1, 1992 and January 15, 1993, although a person whose target date is November 1 could conceivably have his **Close Out Visit** on the first day of the November 1 visit's window, which would be October 17. A person with a target date of November 1 could conceivably have his **Close Out GFR** done on the first day of the November 1 GFR window, which would be October 2. (Note: If a patient reaches a GFR action item any time between October 1 and his or her Close Out Visit, the patient's Close Out GFR can serve as the "repeat due to action item" GFR.)

The Final Follow-Up Visit Folders will be sent to the Clinics the last week of October, so if a patient has a final follow-up visit before November 1, his or her Final Follow-Up Folder will not yet be available and can be mailed to the patient or reviewed with the patient at an extra visit.

If your center is participating in Phase V Study 3 and a patient is having Study 3 samples done at the Close Out Visit, the patient must sign the Phase V Study 3 Informed Consent and have the Study 3 blood and urine collected at the beginning of the visit, before the iothalamate is given. Procedures to be done at Close Out visits include basically all of the procedures done at an annual (F24) visit including the GFR. EKG's will also be done.

The target dates will range from November 1 to December 28. The recommended visit windows will be plus or minus fifteen days. **The actual visit windows for each patient range from fifteen days before his or her target date until January 15, 1993.** The DCC has distributed a list of target visit dates and windows.

3.2 Forms to be Completed and Form Windows

The Close Out Visit type is C. The visit number is 1.0. The forms to be completed at close out are as follows:

FORMS	FINAL FOLLOW-UP VISIT
5 (Monthly Visit)	*
6 (Local Lab)	* (Along with the usual hematology, the local lab should do platelets at the final FU Visit)
13 (Annual Demographics)	*
16,42 (GFR)	*
17*	*(Since all measurements that are ever done are done at Close Out, none of the Form 17 variables need to be labelled "Repeat due to action item")
18,35 (EKG)	*
19,36 (Amino Acids)	*
26 (Symptom Checklist)	*
27 (QWB)	*
28 (SCL90R)	*
29 (HCFA/ECON)	*
32,33** (CBL-Urine & Blood)	*(All blood work normally reported on a Form 33 at F24 will be done at Close Out)
43 MDRD Nutrition Survey Form	*
44 Evaluation Form for Randomized Patients	*
46 (Blood Pressure)	*(Both sitting and standing)
52 (BP Med Changes)	*
53 Study 3 Central Biochemistry Lab Mailing Form (See Appendix 2)	*(Includes Close Out platelet data)
54 Study 3 Central DNA Lab Mailing Form (See Appendix 2)	*
64 (3-Day Diet Diaries)	*
65 (Anthropometry)	*
73 (Pill Counts-Diet K)	*
74 (Dietary Satisfaction)	*
76 (Counselling)	*

77 (Dietitian Time Log)	*
79 Special Products Order Form	*
Phase V Study 3 Informed Consent Form (See Appendix 2)	*(If these samples are being collected at Close Out)

The Stop Point Form (Form 11), Hospitalization Form (Form 10), or Death Form (Form 15) should be completed if applicable.

The windows are the same as for the visit, except for the GFR and anthropometry forms, which have a window from 30 days before target until January 15, and the QWB form, which will have a window for all patients from fifteen days prior to the target until March 15. (Try to schedule the Close Out GFR's on or before January 13, 1993, since iothalamate vials expire on January 13, 1993.)

3.3 Samples to be Collected

Appropriate samples must be collected for the tests on the forms specified above. As of the Close Out Visit, there are no more action items, so regardless of the levels observed at Close Out, no Close Out tests (including GFR) need to be "repeated due to an action item".

For patients who consent to Phase V Study 3, the Close Out Sample Storage Bank, additional samples of blood and urine must be processed following the procedures outlined in Appendix 2. These will be part of the MDRD Sample Storage Bank, and can be submitted *at any time prior to that patient's Close Out.*

3.4 Information to Patient: The Final Follow-Up Visit Folder

The Final Follow-Up Visit Folder will be a grey folder. Unless an item is marked as optional, it should be given to all patients. The folders will be assembled at the DCC and distributed to the Clinics. The folders will include the following items.

Added at Center

a) Certificate and letter of appreciation from National Institutes of Health
b) Copy of the first thank you letter to the referring physician
c) Keeping Track booklets or personalized Protein Counter (optional)

d) Study 3 Informed Consent

Inserted at DCC

e) Nutrition Survey Form 43
f) MDRD Evaluation Form 44
g) Envelope addressed to the DCC
h) "Your Nutrient Prescription"
i) Introduction to Future Studies: Summary of Phase V Plans

Examples of the information for the Final Follow-Up Visit Folder are provided in Appendix 3. In addition, Appendix 3 item j is Form 56, the "Data Form" version of the Nutrient Prescription which will be completed and key entered. Appendix 3 item k is a special handout to be given to keto acid patients.

3.5 Medications and Materials to Patients

Prior to Close Out, the Clinical Center staff should order a sufficient quantity of medications. Each patient will receive at least a three-month supply of all medications normally supplied (including MDRD multivitamins, calcium carbonate, iron, and antihypertensives but not including keto acids). Patients may receive a sufficient supply to last them until Post Close Out #2.

Before the end of the Close Out Visit, make sure the patient receives a 24-hour urine jug and a 3-day diet diary form to bring to the Post Close Out Visit #1.

3.6 Information to Referring Physicians

A letter will be sent from the clinic to the referring physician after the Close Out Visit. This first thank you letter, as shown in Appendix 3, will thank the physician for the patient referral to the MDRD Study and note the patient's participation. Approximate dates for the patients Personal Results (Post Close Out #1) and Study Results (Post Close Out #2) visits will be stated. A statement will be made that their patient's data through the Final Follow-Up Close Out Visit will be available after the Post Close Out #1 Visit and the major MDRD Study results will be available after the Post Close Out #2 Visit.

3.7 Completing the Close Out Data Collection Process

The last Close Out Visit data will be collected on January 15, 1993, so a clean database (complete with all Baseline, Follow-Up, and Close Out forms) is anticipated by January 31, 1993. The EKG Reading Center, the Central Amino Acid Laboratory, and all labs must submit all data to the DCC by January 25, 1993.

4. Personal Results (Post Close Out #1) Visits

4.1 Visit Summary and Visit Windows

Two calendar months after the target date of each patient's Close Out Visit will be the target date for the Personal Results Post Close Out Visit #1. At the Post Close Out #1 visit, the patient will receive his or her Personal Results Folder, his or her individual GFR data, and summaries of his or her MAP and EPI over the course of the study. (If the Post Close Out #1 Visit is not at least 30 days after the date the patient's Close Out data was collected, the folder of the patient's personal results data will be unavailable. Clinics should try to schedule the visits as close to their target dates as possible.)

The Post Close Out #1 Visits will be held between January 1, 1993 and March 15, 1993. Since their target dates are based on the target dates for the close out visits, the target dates of the post close out visits will range from January 1 to February 28, 1993. The recommended visit windows will be plus or minus fifteen days, although no visits can be held before January 1, because the first "Personal Results Folders" will not be available until January 1, 1993. The actual visit windows for each patient range from fifteen days before his or her target date until March 15, 1993.

If the patient begins dialysis anytime after his or her final follow-up (Close Out) visit, the Post Close Out Visit #1 and Post Close Out Visit #2 will be held as described. The patient will not do the 24-hour urine collection, however.

4.2 Forms and Form Windows

The Personal Results Post Close Out #1 Visit type is "Z". The visit number is 1.0. Forms to be completed are as follows:

FORMS	PERSONAL RESULTS VISIT
5 (Monthly Visit)	*
6 (Local Lab)	*
17*	*(Since all measurements that are ever done are done at Close Out, none of the Form 17 variables need to be labelled "Repeat due to action item")
26 (Symptom Checklist)	*
32,33**, (CBL-Urine & Blood)	*(All blood work normally reported on a Form 33 at F24 will be done at Close Out)
46 (Blood Pressure)	*(Seated measurement only)
52 (BP Med Changes)	*
64 (3 Day Food Records)	*
77 (Dietitian Time Log)	*
79 Special Food Products Order Form	*

The Stop Point Form (Form 11) should be completed only if the patient goes on dialysis or has a transplant; no other stop points are declared after the final follow-up visit. The Death Form (Form 15) should be completed if applicable. The form windows will be the same as visit windows.

4.3 Information to be Given to Patient: The Personal Results Folder

The Personal Results Folder will be a black folder with a white label. Unless an item is marked as optional, it should be given to all patients. The folders will be assembled at the DCC and distributed to the Clinics. The folders will include the following; these will be developed by those indicated in italics:

a) GFR, EPI (in grams/day as well as grams/kg/day), and MAP values plotted over time, plus past year's biochemistry flowsheet
b) Protein Phosphorus and Calories
c) Fat, Potassium and Sodium
d) Copy of the second Thank You letter with personal results to the referring physician
e) How has MDRD helped me? How have I made a difference?

f) Nutrition Prescription Form
g) Detailed descriptions of Phase V Study 1
h) Informed consent form for Phase V Study 1 (Note: We give the informed consent to the patient again at the Study Results Visit.)

Examples of these are provided in Appendix 4. The Form 56 should be completed again if the data changes.

4.4 Information to be Given to Referring Physician

The Clinics will send the following to each referring physician:

a) Second Thank You letter to referring physicians (personalized)
b) Patient is GFR, EPI (in grams/day as well as grams/kg/day), and MAP values, plus Patient's Biochemistry Flow Sheet
c) Patient's Protein, Phosphorus and Calories
d) Patients Fat, Potassium and Sodium

Note: The information to be given to the referring physician will be prepared by the DCC and sent to the Clinic with the patient's Personal Results Folder. If desired, the clinics may use the text in the second thank you letter to referring physicians, which is shown in Appendix 4, and personalize the letters by adding:

1. the diet and blood pressure groups to which the patient was assigned
2. a written summary of the patient's personal results, including compliance with the study diet and blood pressure regimens, and an explanation of their significance
3. any medical, dietary, or social service recommendations
4. a brief introduction to Phase V

4.5 Completing the Post Close Out Visit

Before the end of the Post Close Out #1 Visit, the patient should be given a 24-hour urine jug to bring to the Post Close Out #2 Visit. Patients who seem likely to consent to Phase V Study 1 should be given a 3-day diet diary.

4.6 Completing the Post Close Out Data Collection Process

All data from Post Close Out #1 Visits must be submitted by March 31, 1993.

g) Keeping Track booklets or personal protein counters (optional)–*NCC*

Examples of each of these are provided in Appendix 5.

5.3 Information to be Given to Referring Physician

The Clinics will send the following to each referring physician:

a) MDRD Study Results Report

b) Customized Study results letter to the referring physician

Note: The information to be given to the referring physician will be sent to the Clinic with the Study Results Folder. If desired, the clinics may use the Study Results template letter (Appendix 6) and personalize the letter by adding:

1. the diet and blood pressure group to which the patient was assigned
2. a written summary of the study results and an explanation of their significance
3. any medical, dietary, or social service recommendations
4. a description of Phase V

5.4 Use of Post Close Out #2 as "Baseline" for Phase V Study 1

It should be noted that this final debriefing visit of Phase III could serve as an initial Baseline Visit for Phase V Study #1 for patients who are not on dialysis. If a patient is entering Phase V, the additional Phase V data must also be collected at the Post Close Out Visit #2. This will include a GFR at Post Close Out #2 and a QWB interview within 90 days of Post Close Out #2 in addition to the usual Post Close Out #2 data collection.

5.5 Forms and Form Windows

The Post Close Out #2 Visit type is "Z". The visit number is 2.0. The following forms are to be completed:

FORMS	STUDY RESULTS VISITS
5 (Monthly Visit)	*
6 (Local Lab)	*
17*	*(Since all measurements that are ever done are done at Close Out, none of the Form 17 variables need to be labelled "Repeat due to action item")
26 (Symptom Checklist)	*
32,33** (CBL-Urine & Blood)	*(All blood work normally reported on a Form 33 at F24 will be done at Close Out)
46 (Blood Pressure)	*(Seated measurement only)
52 (BP Med Changes)	*
64 3 Day Food Record	*
65 (Anthropometry)	*
77 (Dietitian Time Log)	*
79 Order Form for Special Food Products	*

The Stop Point Form (Form 11) should be completed if the patient has gone on dialysis or has had a transplant; no other stop points are declared after the final follow-up visit. The Death Form (Form 15) should be completed if applicable.

The last Post Close Out #2 Visit data will be collected on June 15, so a clean database is expected by June 30. The Post Close Out #2 Visit data will be used in secondary analyses.

6. Protocol for Close Out of Post Stop Point Patients

6.1 Forms and Form Windows for Close Out

Patients will have their usual visits through October 31. Between November 1, 1992 and February 28, 1993, each Clinical Center should hold the regularly scheduled visit and complete a Form 12 for each Post Stop Point patient. This will be considered the Post Stop Point patient's Close Out Visit. The usual Form 12 data should be collected. Recall that if the patient is not on dialysis and has not had a transplant, a GFR is done at the Post Stop

Phase V, Study 1 Visits and Measures - Revision of 7/20/93

Form	Visit Name:	Z2* "Post Close Out Visit #2"	V4 Follow-Up
	Phase V Visit Month	**0**	**4**
5	Exam & Medication Record	X	X
6	Local Laboratory Measurement	X	X
10	Hospitalizations	X	X
16	GFR	X	X
17	24-Hour Urine	X	X
17	Blood Tests, Fasting	X	
17	Blood Tests, Not Fasting *(This includes phosphorus, BUN, creatinine, albumin and transferrin.)*		X
27	QWB Interview	X	
46	RZ Blood Pressure	X	X
54	*DNA Blood Mailing Form*		X
56	Nutrition Prescription	X	X
64	3-Day Diet Diary	X	X
65	Anthropometry	X	X
77	Time Log	X	
81	*Waist Hip Ratio Form*		X
91	Phase V Enrollment	X	

(Dialysis, transplants, and deaths will be recorded as needed, Forms 11 and 15)

Use Phase V version of the forms for V4.

Phase V, Study 2 Visits and Measures - Revision of 7/20/93

Form	Visit Name:	(Retrospective) Start of Dialysis	Z2 "Post Close Out Visit #2"	V4 Follow-Up
	Phase V Visit Month		**0**	**4**
5	Exam & Medication Record		X	X
10	Hospitalizations		X	X
17	Central Laboratory Blood Tests: Serum albumin Serum transferrin		X	X
27	QWB Interview		X	
46	RZ Blood Pressure		X	X
54	*DNA Blood Mailing Form*			X
55	Dialysis Data Form*	X	X	X
56	Nutrition Prescription		X	X
64	3-Day Diet Diary		X	X
65	Anthropometry		X	X
77	Time Log		X	
81	*Waist Hip Ratio Form*			X
91	Phase V Enrollment		X	

(Transplants and deaths will be recorded as needed, Forms 11 and 15)

Use Phase V version of the forms for V4.

Point Visit. (Try to schedule these post stop point GFR's on or before the December 1992 iothalamate expires on January 13, 1993.) The Abbreviated Visit Forms should be completed. The patient will receive a Post Stop Point Close Out folder. This will be a white folder. It will contain:

Added at Center

a) Certificate and Letter of Appreciation from NIH
b) Copy of first Thank You Letter to referring physician

Inserted at DCC

c) Form 43, Nutrition Survey
d) Form 44, Evaluation Form
e) Envelope addressed to the DCC

Patients should be asked to complete Form 43 and Form 44, the Nutrition Survey Form and the Evaluation Form for Randomized Patients. The patients will receive a letter of appreciation.

The visit type will be A, as is usual for Abbreviated visits. The Close Out visit number will be the usual visit number. The target date will be the patient's usual target. The window will be minus 30 days up until April 30. Phone interviews will be acceptable, but visits are strongly preferred. If the patient has died, a Form 15 should be completed.

6.2 Post Stop Point Study Results Visits

These patients will be invited back for Post Stop Point study results visits in April or May. At these visits, the patients will receive the Post Stop Point Study Results Folders, a light blue folder which includes those patients' "Personal Results" as well as the MDRD Study Results Reports and Phase V information.

At these Post Stop Point Study Results Visits, the patients who are on hemodialysis or peritoneal dialysis will be asked to consent to Phase V Study #2 for dialysis patients. A description of Phase V Study 2, the new dialysis data collection form, and informed consent form for Phase V Study 2 are given in Appendix 6. If the patient is not eligible for Phase V Study 2, or if the patient does not consent to enter Phase V Study 2, no data is collected at this visit.

6.3 Use of Post Close Out #2 as "Baseline" for Phase V Study 2

If the Post Stop Point Study Results Visit is used as an initial Phase V Study 2 Visit for a patient on dialysis, the following data must also be collected at the visit:

Blood Tests:
- Serum albumin
- Serum transferrin
- Lipid profile

Diet Prescription
3-Day Diet Diary
Anthropometry
Medication Record
RZ Blood Pressure
QWB Interview (within 90 days)
Hospitalizations

7. Protocol for Phase III Close Out of Study F Patients

Patients will have their usual visits through November 30. Between December 1 and May 30, 1993, each clinical center should complete a Form 47 for each Study F patient. This will be considered the Study F Close Out Visit. Patients should be asked to complete Form 45, the Evaluation Form for Study F patients. The patients will also receive letters of appreciation. Form 45 and a draft letter of appreciation are shown in Appendix 7.

The visit type will be X, as is usual for Study F visits. The visit number will be the patient's usual visit number. The target date will be the patient's usual target in those six months. The window will be minus 30 days up until May 30. Phone interviews will be acceptable, but visits are strongly preferred. The usual Study F data should be collected, and the usual forms should be completed. If the patient has died, a form 15 should be completed.

8. Disseminating Study Results

8.1 Updating the Major Results Paper

After the Close Out Data Collection Process is completed in January, the DCC will have four weeks (February 1 through February 28) to use the January 31 database to prepare an update of the Phase III Major Results Paper. The DCC will use the EMC's revision of the draft paper will be reviewed in January. (The event data in this paper will not be complete,

since we will learn more about patients reaching dialysis after close out when patients come to the Personal Results (Close Out #1) Visits.)

A meeting of the Steering Committee will be convened in early March to approve the Major Results paper. The meeting has been scheduled for March 8 and 9, 1993. At the beginning of the meeting, Steering Committee members will be given a numbered draft of the paper and will be given several hours to read the paper. The Steering Committee will then convene and discuss the paper, and suggest revisions. After the meeting, the draft copies will be collected. A draft agenda for the meeting is as follows:

March 8

12:00 noon	Draft "Major Results Paper" Available
6:00 p.m.	Steering Committee Convenes
8:00 p.m.	Subcommittees Convene

March 9

8:00 a.m.	Steering Committee Convenes
12:00 noon	Steering Committee Adjourns
1:00-3:00 p.m.	Writing Committees Meet

The Executive Committee will revise the paper and it will be submitted for publication to the journal selected. (This is assuming that only minor revisions are required, so no additional Steering Committee review is required.) The paper will be submitted as soon as possible in the hope that it would be published as soon as possible. The second press conference, which will include study results, will be held in conjunction with publication.

8.2 Plans for the Press Conference: Results of Slopes

The MDRD Press Conference is anticipated to be held in April of 1993. The first press conference will not include study results. The last Close Out Visit data will be collected on January 15, 1993, so a clean database (complete through Close Out) is anticipated by January 31, 1993. Between April 1, 1993 and June 15, 1993, the Post Close Out #2 Visits will be occurring and the patients will be receiving the slope information which is the key part of the major results paper.

8.3 Later Results: Time to Events

The last Post Close Out #1 Visit data will be collected on March 15, 1993, so a clean database (complete through Post Close Out #1) is anticipated by March 31, 1993. The DCC will use these data to update the events analyses in the Phase III Major Results Paper; this will be done by April 15, 1993. This update is important since it is anticipated that a number of patients will go on dialysis after the Close Out visits; this was observed in the MDRD Pilot Study.

Although it is important to submit the Major Results paper as soon as possible, if the Major Results paper is submitted prior to April 15, the complete event rate data for MDRD patients reaching dialysis cannot be included.

8.4 Phase V: Enrollment Form

The instructions and the Phase V Enrollment Form are on the following pages.

Modification of Diet in Renal Disease Study
Phase V Enrollment

This form is to be completed by the Study Coordinator when a patient is enrolling in Phase V.

QUESTION #	INSTRUCTIONS
4.	Indicate which Phase V study the patient is enrolling based on the eligibility criteria in the Close Out Manual of Operations.
5.	The patient must sign a new informed consent for Phase V.

Modification of Diet in Renal Disease Study
Phase V Enrollment Form

This form is to be completed by the Clinical Center when a patient enters Phase V.

FORM # 9 1

1. Patient Identification Number ..... ___ ___ ___ ___ ___ ___

2. Patient Name Code ..... ___ ___ ___ ___

3. Clinical Center ..... ___ ___

4. Which Phase V Study is this patient enrolling in? ..... ___
   1 = Study 1 (non-dialysis patients)
   2 = Study 2 (dialysis patients)

5. a. Has the patient signed the appropriate Informed Consent Form for Phase V? (1 = yes, 2 = no) ..... ___

   b. Date form sent to Data Coordinating Center ..... ___ ___/ ___ ___/ ___ ___

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 ..... ___ ___ ___ ___ ___

Appendix 1

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The "What's Next?" Handout

Here's what you can expect in the MDRD Study over the next several months. Please let us know if you have any questions.

Before the Final Follow-Up Visit

- Continue to follow your MDRD Study eating pattern and blood pressure goals.

Final Follow-Up Visit

- Have a clinic visit (includes GFR and EKG).
- Fill out a survey about the MDRD Study in general and one about the MDRD Study Nutrition Program. The local clinic staff will not see your answers.
- Discuss your dietary and blood pressure prescription.
- Learn where to get special food products, supplements, and medical and nutrition care after the MDRD Study ends.
- Learn about the ongoing kidney studies you may be able to take part in.

Between the Final Follow-Up Visit and Personal Results Visit

- Continue to see your personal doctor as needed for health care.
- Follow the eating pattern and blood pressure goals given to you.

Personal Results Visit (about two months after the Final Follow-Up Visit)

- Have a clinic visit (no GFR or EKG).
- Review your dietary and blood pressure prescription.
- Learn how the following have changed since the beginning of the MDRD Study:
  - your kidney function (GFR)
  - your estimated protein intake (EPI)
  - your blood pressure (MAP)
  - your nutrient values
- Learn more about the ongoing kidney studies you may be able to take part in.

Study Results Visit (about three months after the Personal Results Visit)

- Have a clinic visit (no GFR or EKG).
- Learn the MDRD Study study-wide results and how they apply to your dietary and blood pressure prescription.
- Sign a consent form if you want to take part in an ongoing kidney study.

About the MDRD Study Nutrition Program Survey

You will be given a survey about the MDRD Study Nutrition Program on _____.

The two-page survey asks you:

- which parts of the MDRD Study Nutrition Program were useful to you.
- to name five MDRD Study handouts that were useful to you and explain why.
- to name five MDRD Study handouts that were not useful to you and explain why.

To get ready for the questions on the handouts, please:

1. **Review your MDRD handouts at home** before you come in for the survey. Think about which ones you found useful or not and why.
2. **Bring all of your MDRD handouts with you when you come in for the survey.** This will help you remember the handouts you have used.

Thank you. Your thoughts about the MDRD Study Nutrition Program are very important to us.

Appendix 2

Study 3, The Close Out Sample Storage Bank

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a. STUDY 3 PROTOCOL

Protocol for Study 3

Eligibility criteria for plasma and urine: Patients in Study A and Study B who consent to have additional urine collected and blood drawn at the beginning of the Phase III Close-Out Visit or the visit before iothalamate injection are eligible. Patients need not have been fasting prior to the visit at which Phase V Study 3 specimens are drawn. The total amount of blood required for the following sample is 20 ml. It is anticipated that this study will require only administrative approval from the clinical center investigational review boards. A consent form has been prepared for New England Medical Center. Other clinical centers can use this as a model. This Study 3 consent form, "Consent for additional blood and urine samples," is attached.

The plasma and urine will be frozen to -70°C and sent to the MDRD Central Biochemistry Laboratory on dry ice.

Eligibility criteria for whole blood for DNA: Patients who consent at the time the DNA blood is drawn. (This will not be done at the Close Out Visit.) The heparinized blood will be drawn, chilled and sent to the MDRD Central Peripheral Leukocytes for DNA Testing Laboratory (to be named at a later date) where the leukocytes will be separated from the blood and frozen at -70°C for future isolation of DNA.

Plasma

1. Heparinized plasma which is iced immediately after drawing, centrifuged at 3000 G for 5 minutes within 30 minutes in a refrigerated centrifuge, and then stored at -70°C. The specimens will allow for the measurement of certain plasma cytokines. The plasma from one 10 ml heparinized test tube should be saved. Approximately 2 ml of plasma should be placed into each of two 1.8 ml plastic tubes that can be stored at -70°C. Care should be taken so that the plasma specimens are not contaminated by leukocytes or red cells.

2. EDTA plasma which is iced immediately after drawing, centrifuged at 3000 G for 5 minutes within 30 minutes in a refrigerated centrifuge, and then stored at -70°C. This specimen will permit the measurement of calcium and magnesium-dependent substances, such as complement. The plasma from two 5 ml EDTA test tubes should be saved. Approximately 2 ml of plasma should be placed into each of two 1.8 ml plastic test tubes that can be stored at -70°C. Care should be taken so that the plasma specimens are not contaminated by leukocytes or red cells.

Urine

3. Urine which has been collected over 24 hours in acetic acid and then stored at -70°C. (This is to be taken from the Close Out 24-hour urine.) This will allow the measurement of

constituents which have variable excretion rates over a 24-hour period and which require preservation by acid. Urine ammonium is an example. Four 5 ml aliquots of urine should be centrifuged at moderate speed for 5 minutes to remove suspended material. Approximately 5 ml of urine supernatant should be removed from each centrifuge tube and added to each of four 4.5 ml plastic test tubes which are stored at -70°C. The volume of the 24-hour urine should be recorded on the tubes' label.

4. Freshly voided urine (voided before iothalamate injection) which should be iced immediately after voiding, centrifuged for 5 minutes in a refrigerated centrifuge, and then stored at -70°C. The purpose of this specimen is to collect urine for measurement of substances such as thromboxane which might be degraded in an unrefrigerated urine sample or denatured by acetic acid. (An extra freshly voided single specimen is obtained at the Close Out Visit rather than a refrigerated 24-hour specimen because of the uncertainty that the 24-hour specimen was refrigerated properly.) The freshly voided urine specimen should be centrifuged at moderate speed for 5 minutes in a refrigerated centrifuge, as described above, and four 4.5 ml aliquots of urine saved, as described above.

Whole Blood for DNA

5. Heparinized blood which is refrigerated. The purpose of this sample is to obtain leukocyte fractions for isolation of DNA. Blood should be drawn into five 10 ml heparinized test tubes and stored in a refrigerator (samples should not be frozen). The samples will be sent in the tubes in which it was drawn to the Central DNA Laboratory (to be named). The final protocol for the collection and preparation of these samples has not yet been determined. This will not be done until the Close Out Visit.

b. NEMCH/MGH Example Consent

MODIFICATION OF DIET IN RENAL DISEASE STUDY

CONSENT FOR ADDITIONAL BLOOD AND URINE SAMPLES

Institution: New England Medical Center Hospitals
Principal Investigator: Andrew S. Levey, M.D.
Co-Investigators: Cecil H. Coggins, M.D.
Andrew J. King, M.D.

I am enrolled in the Modification of Diet in Renal Disease Study to determine whether or not dietary protein and phosphorus restriction and/or strict control of blood pressure slows the progression of kidney disease. I am being asked to give consent for additional blood samples (approximately 70 ml.) and an additional urine sample. The blood samples would be obtained at the time of a regularly scheduled blood draw. The urine sample would be obtained from a regularly scheduled urine collection.

PURPOSE: The purpose of the additional blood and urine samples is to perform laboratory tests that were not anticipated at the beginning of the study. The purpose of the tests is to provide additional measures of the usefulness and safety of the dietary and blood pressure regimens that I have been following.

RISKS: There are no additional risks involved to providing these samples. There is a risk of possible bruising or discomfort at the site from the regularly scheduled blood draw.

BENEFITS: There is no direct benefit to me in providing these extra samples. The indirect benefit may include that other people may benefit in the future from the information learned.

PRINCIPAL INVESTIGATOR'S PHONE NUMBERS

If I have any further questions about these samples or experience any difficulties, I may contact Dr. Levey at (617) 956-5866 or 956-5114 (NEMCH page).

PARTICIPANT'S STATEMENT

I have read this consent form and have discussed with Dr. _____ or his representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or if I prefer, with a written statement.

I understand that I will be informed of any new significant findings developed during the course of this research study.

I understand that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue my participation in this study at any time, I will be free to do so, and this will have no effect on my future care or treatment by my physicians or this hospital.

I understand that in the event I become ill or am injured as a result of participating in this research study, medical care will be provided to me. However, such medical care will not be provided free of charge, even if the illness is a direct result of this research study. I understand that no funds to provide financial compensation for research related injury or illness are available.

If I have any questions concerning my rights as a research subject in this study, I may contact the Human Investigation Review Committee at (617) 956-7512.

I understand that as a participant in this study my identity and my medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the U.S. Food and Drug Administration which regulates investigational drug studies, and the study sponsor, NIH (National Institutes of Health).

A signed copy of my consent form will be kept on record at the Data Coordinating Center. This well be kept confidential and not stored with other study records.

I have been fully informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above. I have received a copy of this consent form.

_____
Participant

I have fully explained to _____ the nature and purpose of the above-described study in this consent form, including the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____
Principal Investigator or Representative

_____ _____
Date Witness

c. Addendum to "Consent for Additional Blood and Urine Samples"

1. You are being invited to participate in a protocol addition to the original MDRD Study. We are asking the MDRD participants to have additional blood drawn for a genetic study separate from the usual blood test done as part of the MDRD Study.

   A. A 50 milliliter blood sample (equivalent to approximately three tablespoons) taken from you will be saved to try to identify genes. The purpose of this sample is to obtain leukocyte fractions for isolation of DNA. Purified genetic material (DNA) from the cells in my blood will be prepared, and at a later time permanent cell lines may also be established so that additional genetic studies can be done. These specimens will belong to the MDRD Research Group and, as such, will be used for research purposes only.

   B. You are being asked to allow storage of DNA; exactly what tests will be completed, such as HLA typing, will be decided at a later time.

2. There are certain risks and discomforts that might be associated with this research:

   Blood drawing may be associated with minor discomfort. A bruise may occur at the site of blood drawing and last 1-2 days.

3. Participation in these studies is strictly voluntary. You may choose not to participate in this research; whatever your decision, it will not at any time affect the commitment of your health care providers to administer optimal care. Refusal to participate in these studies will not jeopardize your ability to receive medical care through the Clinical Center nor will it jeopardize your participation in the MDRD Study.

d. Tube Labelling for Phase V Study 3 - The Close Out Storage Bank

Each tube will be labelled using special labels provided by the Central Biochemistry Laboratory and certified for storage at -70°C.

Tubes should be labelled with:

ID
Namecode
Clinic
Date: For blood or plasma, date blood drawn. For urine, date 24-hour urine collection was completed or date urine was voided.
Volume: For 24-hour urine aliquot, the volume of the complete urine collection.

Sample Type:

HP for Heparinized Plasma
EP for EDTA Plasma
24U for 24-Hour Urine
FVU for Freshly Voided Urine
HWB for Heparinized Whole Blood

Sample Sequence "Number of Number":

For example, "1 of 2" and "2 of 2" for plasma or "3 of 4" for 24-hour urine.

e. MDRD Phase V Study 3 Enrollment and Mailing Form

This form is for the plasma and urine for Study 3, the MDRD Close Out Sample Storage Bank. It can be done at any visit up until Close Out, as soon as the patient has consented. The form will be sent with the specimens to the Central Biochemistry Laboratory. When it is complete, key enter and transmit to the DCC.

1. ID . . . . . __ __ __ __ __ __
2. Namecode . . . . . __ __ __ __
3. Clinic . . . . . __ __

Platelets

4. Platelet value from the Close Out Visit . . . . . __ __ __ , __ __ __

Enrollment

5. Did the patient sign the Study 3 consent form? (1=yes, 2=no) . . . . . __
6. Date consent form signed . . . . . __ __/__ __/__ __

Plasma

7. How many tubes of heparinized plasma have been sent? (0, 1 or 2) . . . . . __
8. Date heparinized plasma drawn . . . . . __ __/__ __/__ __
9. Date heparinized plasma sent . . . . . __ __/__ __/__ __
10. How many tubes of EDTA plasma have been sent? (0, 1 or 2) . . . . . __
11. Date EDTA plasma drawn . . . . . __ __/__ __/__ __
12. Date EDTA plasma sent . . . . . __ __/__ __/__ __

Urine

13. How many extra aliquots of the 24-hour urine have been sent? (0, 1, 2, 3 or 4) __
14. Date urine collection completed . . . . . __ __/__ __/__ __
15. Volume of 24-hour urine (including acetic acid)ml . . . . . __ __ __ __
16. Date urine sent . . . . . __ __/__ __/__ __
17. How many tubes of freshly voided urine have been sent? (0, 1, 2, 3 or 4) . . . . __

18. Date urine voided . . . . . __ __/__ __/__ __
19. Date urine sent . . . . . __ __/__ __/__ __

101. Date this form completed . . . . . __ __/__ __/__ __
102. Certification number of person completing this form . . . . . _____
103. Date form entered . . . . . __ __/__ __/__ __
104. Certification number of person entering form . . . . . _____

For Central Biochemistry Use Only

Date samples received . . . . . __ __/__ __/__ __

Comments on samples:

f. MDRD Study 3 Heparinized Blood Mailing Form
Revision of 9/24/92

This form is for the heparinized blood for Study 3, the MDRD Close Out Sample Storage Bank. The form will be sent with the specimens to the Central DNA Laboratory (to be named).

1. ID . . . . . __ __ __ __ __ __
2. Namecode . . . . . __ __ __ __
3. Clinical Center . . . . . __ __
4. How many tubes of heparinized blood have been sent? (0, 1, 2, 3, 4, or 5) . . . __
5. Date blood drawn . . . . . __ __/__ __/__ __
6. Date blood sent . . . . . __ __/__ __/__ __

101. Date this form completed . . . . . __ __/__ __/__ __
102. Certification number of person completing this form . . . . . __ __ __ __ __

Appendix 3

The Final Follow-Up Visit Folder

Table of Contents

Modification of Diet in Renal Disease Study
BLOOD SAMPLES FOR FUTURE DNA MEASUREMENT FORM AND INSTRUCTIONS FOR BUFFY COAT SPECIMENS

Buffy coat specimens

1. Draw blood into a 10 ml. EDTA tube.

2. Spin down in a bench-top centrifuge.

3. Aspirate the plasma with a pipette and discard the plasma.

4. Using a pipette, aspirate the buffy coat off the top of the packed red blood cells.

5. Place the buffy coat in the two 7 ml. freezer tubes provided by the MDRD CBL and express mail them immediately to the Central Biochemistry Lab with Form 54. The samples will be frozen at the CBL. Do not freeze them prior to mailing them.

Modification of Diet in Renal Disease Study
Blood Samples for Future DNA Measurement

This form is for the blood samples for future DNA measurement. The form will be sent with the specimens to the MDRD Central Biochemistry Laboratory.

1. Patient Identification Number ..... _ _ _ _ _ _
2. Namecode ..... _ _ _ _
3. Clinical Center ..... _ _
4. Date blood drawn ..... _ _/_ _/_ _
5. Visit type V
6. Visit number 4.0
7. How many freezer tubes of buffy coat have been sent? (0, 1, 2) ..... _
8. Date tubes sent to lab ..... _ _/_ _/_ _

101. Date this form completed ..... _ _/_ _/_ _
102. Certification number of person completing this form ..... _ _ _ _ _
103. Date this form entered ..... _ _/_ _/_ _
104. Certification number of person entering this form ..... _ _ _ _ _

Final Follow-Up Visit Folder

a. Certificate and letter of appreciation from the NIH

a1: Sample Certificate from NIH

a2: Example Letter of Appreciation from NIH

Final Follow-Up Visit Folder

b. First Thank You Letter to Referring Physician

Note: This letter must be personalized at each center and placed in the folder at each center.

Dear Dr. _____:

The Modification of Diet in Renal Disease (MDRD) Study is completed. Your patient, _ _____, helped make this study a success and your encouragement of patient participation was the necessary step to successful completion. We thank you for your support during this important study.

The results of the study are being analyzed and you will receive information given to your patient about their personal results and the overall study results. Two Post Close Out Visits are planned, the first being two months after the final visit and the second three months later. During the first Post Close Out Visit, the patient will receive his or her personal results folder. The information in this folder shows how he or she did over the course of the study with regard to GFR, level of blood pressure control, dietary protein, phosphorus, fat, sodium, potassium, and calorie intake compared to their assigned goals. During the second Post Close Out Visit, a study results folder will explain the overall study results.

Follow-up studies are being planned for a cohort of MDRD patients so as to obtain additional longitudinal information. Any such studies will be much less intensive than the current study. We will be in touch when we finalize our recommendations on this issue for your patient. Once again we will need your support if we ask your patient to participate in one of these studies.

Thank you for all your support throughout the MDRD study.

Sincerely,

_____, M.D.

for the MDRD Study

Final Follow-Up Visit Folder

c. "Keeping Track" booklets or "Personal Protein Counters"

At each center, the study team may place the usual MDRD "Keeping Track" booklets or "Personal Protein Counters" in the Final Follow-Up Visit Folders, as desired.

Final Follow-Up Visit Folder

d. Study 3 Informed Consent

For each center that is participating in Study 3, the Close Out Sample Storage Bank, the study team will place the center's own IRB-Approved Study 3 Informed Consent Form in the Final Follow-Up Visit Folder. An example was shown in Appendix 2.

It is important that this form be signed by the patient at the very beginning of the Final Follow-Up Visit, since the Study 3 blood samples must be drawn before iothalamate is given.

Final Follow-Up Visit Folder

e. Modification of Diet in Renal Disease Study
MDRD Study Nutrition Program Survey

Your honest thoughts and feelings about the MDRD Study are important to us. Your answers to this survey will help us learn what you liked and did not like about the MDRD Study. Your answers will also help us to better prepare for future studies. Please answer all of the questions, place the survey in the envelope with the Study Survey, and seal it. The sealed envelope will be sent unopened to the MDRD Data Coordinating Center in Cleveland, Ohio.

No one at your clinical center will see your answers to this survey. Your answers will be kept strictly confidential.

Note: Please ask the MDRD Study dietitian if you need help with any of the titles of the MDRD Study handouts (for questions 21 and 22).

Thank you.

Modification of Diet in Renal Disease Study
MDRD Study Nutrition Program Survey

1. How successful do you think you were in meeting your MDRD Study goals?		Very Successful	Successful	No Opinion	Not Very Successful	Not At All Successful
In your efforts to meet your MDRD goals, how useful to you were:	Didn't Get	Very Useful	Useful	No Opinion	Not Useful	Not At All Useful
2. computer printouts (Nutrient Summary Report) from your food records						
3. special food products given to you						
4. your lab test results, **not** including UNA (EPI)						
5. UNA (EPI) results from 24-hour urines						
6. counseling and support from the dietitian						
7. monthly visits						
8. contacts (calls, letters...) between visits						
9. the MDRD computer program (CDDT) and materials developed from it (individualized menus...)						
10. the Protein Wise Counter						
11. Keeping Track of what you ate						
12. weighing and measuring tools (scale, etc.)						
13. Shopping Wise						
14. MDRD Study recipes						
15. Food tasting sessions						
In maintaining your interest in the MDRD Study, how helpful were:	Didn't Attend or Get	Very Helpful	Helpful	No Opinion	Not Helpful	Not At All Helpful
16. special events (dinners, speakers, etc.)						
17. group meetings						
18. MDRD Study appreciation gifts (mugs, rulers...)						
19. newsletters/letters						

Modification of Diet in Renal Disease Study
MDRD Study Nutrition Program Survey

20. What else helped you meet your MDRD Study goals and stay interested in the Study?

What did not help?

_____ _____

_____ _____

_____ _____

21. Please name five MDRD Study handouts that you found most useful and explain why. (Do not include the Protein Wise Counter, Keeping Track, Shopping Wise, or recipes.)

Handout Title	Why Useful	NCC Use Only
a.		__ __ __
b.		__ __ __
c.		__ __ __
d.		__ __ __
e.		__ __ __

22. Please name five MDRD Study handouts that you found least useful and explain why. (Do not include the Protein Wise Counter, Keeping Track, Shopping Wise, or recipes.)

Handout Title	Why Not Useful	NCC Use Only
a.		__ __ __
b.		__ __ __
c.		__ __ __
d.		__ __ __
e.		__ __ __

General comments on the MDRD Study handouts_____

_____

_____

_____

Date form completed __ __/__ __/__ __

Thank you.

f. Modification of Diet in Renal Disease Study
MDRD Study Survey for Randomized Patients

Your honest thoughts and feelings about the MDRD Study are important to us. Your answers to this survey will help us learn what you liked and did not like about the MDRD Study. Your answers will also help us to better prepare for future studies. Please answer all of the questions, place your Study Survey Form in the envelope with the Nutrition Program Survey, and seal it. The sealed envelope will be sent unopened to the MDRD Data Coordinating Center in Cleveland, Ohio.

No one at your clinical center will see your answers to this survey. Your answers will be kept strictly confidential.

Please circle a Y for yes and N for no.

1. Study Intervention

A.	Were you asked to make changes in the foods you eat to meet MDRD goals for protein intake?	Y	N
B.	Were you asked to make changes in the foods you eat to meet MDRD goals for phosphorus intake?	Y	N
C.	Were you asked to make changes in the foods you eat to meet MDRD goals for blood pressure?	Y	N
D.	Were you asked to change your weight to meet MDRD goals for blood pressure?	Y	N
E.	Were you asked to change your exercise to meet MDRD goals for blood pressure?	Y	N
F.	Were you asked to change your prescribed medicines to meet MDRD goals for blood pressure?	Y	N

Modification of Diet in Renal Disease Study
MDRD Study Survey for Randomized Patients

2. Why did you decide to take part in the MDRD Study?

A.	Free medical services.	Y	N
B.	Close, frequent medical monitoring.	Y	N
C.	Reassurance.	Y	N
D.	Hope for physical improvement.	Y	N
E.	To help others with kidney disease.	Y	N
F.	To take part in research.	Y	N
G.	My doctor recommended it.	Y	N
H.	My family wanted me to be in the study.	Y	N
I.	It seemed harmless.	Y	N
J.	Curiosity - I wanted to give it a try.	Y	N
K.	Had time available.	Y	N
L.	Other (please state)_____		

3. Have any of the items below been a problem for you in the MDRD Study?

1 = Never
2 = Rarely
3 = Sometimes
4 = Often
5 = Always

1 2 3 4 5	A.	Travel to and from the clinic
1 2 3 4 5	B.	Parking
1 2 3 4 5	C.	Location of clinic
1 2 3 4 5	D.	Long waits for clinic visits
1 2 3 4 5	E.	Hurried clinic visits
1 2 3 4 5	F.	Too much time spent in clinic visits
1 2 3 4 5	G.	Too many clinic visits

Modification of Diet in Renal Disease Study
MDRD Study Survey for Randomized Patients

3. Have any of the items below been a problem for you in the MDRD Study? (continued)

1 = Never
2 = Rarely
3 = Sometimes
4 = Often
5 = Always

1	2	3	4	5	H.	Inconvenient scheduling of visits
1	2	3	4	5	I.	Changes in the staff at the MDRD Clinic
1	2	3	4	5	J.	Work-related problems
1	2	3	4	5	K.	Family problems related to my attending visits
1	2	3	4	5	L.	Family problems related to my eating pattern
1	2	3	4	5	M.	Side effects from blood pressure medicine
1	2	3	4	5	N.	Side effects from keto acids

4. Who do you feel was helped by your taking part in the MDRD Study?

A. Myself	Y	N
B. Scientists	Y	N
C. The MDRD staff	Y	N
D. Other people with kidney disease	Y	N
E. My family members	Y	N
F. My friends	Y	N

G. Other (please state)_____

Modification of Diet in Renal Disease Study
MDRD Study Survey for Randomized Patients

5. How did the MDRD Study help you?

A. Treatment and information from kidney doctors	Y	N
B. A "second opinion" on my kidney disease	Y	N
C. Treatment and information from dietitians	Y	N
D. Meeting with other people with kidney disease	Y	N
E. Meeting with other concerned people	Y	N
F. More knowledge of my physical condition	Y	N
G. Close monitoring of my physical condition	Y	N
H. Free exams	Y	N
I. Free lab results	Y	N
J. Free medicine	Y	N
K. Personal awareness and education	Y	N
L. Peace of mind	Y	N

M. Other (please state)_____

6. You have met with several staff people during your MDRD clinic visits. How do you rate their treatment of you? Please circle the number that matches your rating for each staff person listed below.

1 = Excellent
2 = Good
3 = Average
4 = Below Average
5 = Poor

1 2 3 4 5	A.	Study doctors
1 2 3 4 5	B.	Study dietitians
1 2 3 4 5	C.	The person who did your GFR measurements
1 2 3 4 5	D.	The study coordinator
1 2 3 4 5	E.	Other study staff people

Modification of Diet in Renal Disease Study
MDRD Study Survey for Randomized Patients

7. The MDRD Study has placed a number of demands on you. Please rate the items below on a scale from 1 to 5 where:

1 = NOT at all unpleasant or difficult;
5 = EXTREMELY unpleasant or difficult.

1	2	3	4	5	A.	GFR
1	2	3	4	5	B.	Blood tests
1	2	3	4	5	C.	24-hour urine collection
1	2	3	4	5	D.	Three-day food records
1	2	3	4	5	E.	Quality of well-being telephone interview
1	2	3	4	5	F.	Psychological Questionnaire (SCL-90-R)
1	2	3	4	5	G.	Blood pressure measurement
1	2	3	4	5	H.	Changes in eating habits
1	2	3	4	5	I.	Blood pressure medicine

8. For each statement below, please show how much you agree or disagree on a scale from 1 to 5 where:

1 = Strongly Agree
2 = Agree Somewhat
3 = Undecided
4 = Disagree Somewhat
5 = Strongly Disagree

1	2	3	4	5	A.	My decision to take part in the MDRD Study was a good idea.
1	2	3	4	5	B.	The results of the MDRD Study will be of great value to people with kidney disease.
1	2	3	4	5	C.	Taking part in the MDRD Study helped my kidney disease.

Modification of Diet in Renal Disease Study
MDRD Study Survey for Randomized Patients

8. For each statement below, please show how much you agree or disagree on a scale from 1 to 5 where: (continued)

1 = Strongly Agree
2 = Agree Somewhat
3 = Undecided
4 = Disagree Somewhat
5 = Strongly Disagree

1 2 3 4 5	D.	I would make changes in my own life if the final results of the MDRD Study showed that I would be more healthy.
1 2 3 4 5	E.	Taking part in the MDRD Study helped my health in general.
1 2 3 4 5	F.	The protein and phosphorus levels of my study diet were clear to me.
1 2 3 4 5	G.	I was successful in meeting my dietary goals.
1 2 3 4 5	H.	I am happy with the study diet to which I was assigned.
1 2 3 4 5	I.	Following my study diet made me feel much better.
1 2 3 4 5	J.	My study goal for blood pressure was clear to me.
1 2 3 4 5	K.	I was successful in meeting my blood pressure goals.
1 2 3 4 5	L.	I am happy with the study goal for blood pressure which I was assigned.
1 2 3 4 5	M.	Keeping my blood pressure below the level of my study goal has made me feel much better.
1 2 3 4 5	N.	My family and friends supported my taking part in the study.
1 2 3 4 5	O.	<u>For those now employed outside the home:</u> My employer supported my taking part in the MDRD Study.

Modification of Diet in Renal Disease Study
MDRD Study Survey for Randomized Patients

9.	**If you were asked in the future to take part in a study like MDRD, do you think you would volunteer?**	**Y**	**N**
10.	**Would you recommend taking part in a study like MDRD to a friend or a family member who was thinking about volunteering?**	**Y**	**N**
11.	**Date form completed**	__ __/__ __/__ __	

Please feel free to write any other comments in the space below or on the back of this form. These comments will be read and summarized confidentially by the people who work at the MDRD Data Coordinating Center at The Cleveland Clinic Foundation in Cleveland, Ohio. Your comments will not be shown to any of the staff members at your MDRD clinic.

Final Follow-Up Visit Folder

g. Envelope Addressed to the DCC

Each patient folder will contain a stamped white 6½ by 9½ envelope with a label addressed as follows:

MDRD Data Coordinating Center
Attention: Ms. Mary Brown
Department of Biostatistics and Epidemiology, Desk P88
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195-5196

The envelopes are made of recycled white woven paper and will fit in the Follow-Up Visit Folders. The envelopes easily hold Forms 43 and 44 if the forms are folded in half.

Final Follow-Up Visit Folder

h. "Your Nutrient Prescription"

For _____ Date _____

Protein _____ grams/day

Phosphorus _____ milligrams/day

Calories _____ to _____ kilocalories/day

Sodium _____ to _____ milligrams/day

Multi-vitamins _____ tablets/day _____

Calcium _____ mg/day _____

Iron _____ mg/day _____

Other_____

_____

_____

_____

_____

_____

_____

_____

_____ _____

P/All/15/9-92

Final Follow-Up Visit Folder

i. Future Kidney Disease Studies

Three important new studies of chronic kidney disease will be conducted soon at the MDRD Study clinical centers. Please begin thinking about taking part in these studies.

Compared to the MDRD Study, the new studies feature:

- Fewer clinic visits,
- Flexible study goals: You can take part no matter which nutrition or blood pressure regimen you choose to follow,
- Any lab test results, including GFR, will be given to you during the study,
- Only two GFR tests (Study 1 and 2).

	Study 1	Study 2
Who can take part?	Anyone **not on dialysis** who took part in the MDRD Study	Anyone **on dialysis** who took part in the MDRD Study
Purpose and benefits to you	To monitor your kidney function, blood pressure, nutrition, and general health	To monitor your kidney function, blood pressure, nutrition, and general health
Length of study	About 1 year	About 1 year
Number of clinic visits	3 visits (one every 4 months)	2 visits (one after 4 months and one at the end)
Will I get nutrition counseling?	Yes, to help you follow a healthy eating pattern	Yes, to help you follow a healthy eating pattern
What will happen at each visit?	Nutrition prescription, blood pressure, 3-day food record, 24-hour urine, blood tests, anthropometry, GFR (at two visits only)	Nutrition prescription, blood pressure, 3-day food record, blood tests, anthropometry

j. Modification of Diet in Renal Disease Study
Close Out Period Nutrition Prescription Form

Indicate prescription patient agrees to follow. You may skip any nutrients that are not prescribed. Complete at the Close Out Visit for all randomized patients. Complete at Post Close Out #1 and Post Close Out #2 if there are any changes.

1. Patient Identification Number . . . . . __ __ __ __ __ __
2. Patient Namecode . . . . . __ __ __ __
3. Clinical Center . . . . . __ __
4. a. Date of Visit . . . . . __ __/__ __/__ __
   b. Visit Type . . . . . __
   c. Visit Number . . . . . __ __.__
5. Protein (grams/day) . . . . . __ __ __.__ __
6. High biological value protein (grams/day) . . . . . __ __ __.__ __
7. Phosphorus (milligrams/day) (mean) . . . . . __ __ __ __
8. Calories (kilocalories/day)
   a. Minimum . . . . . __ __ __ __
   b. Maximum . . . . . __ __ __ __
9. Sodium (milligrams/day)
   a. Minimum . . . . . __ __ __ __
   b. Maximum . . . . . __ __ __ __
10. Multi-vitamins (tablets/day) . . . . . __
11. Calcium (mg/day) (elemental calcium from supplements) . . . . . __ __ __ __
12. Iron (mg/day) (elemental iron from supplements) . . . . . __ __ __ __
13. Potassium (mg/day) (only if for dietary restriction) . . . . . __ __ __ __

Other Comments: _____

_____

101. Date this form completed . . . . . __ __/__ __/__ __
102. Certification number of dietitian completing this form . . . . . __ __ __ __ __
103. Date form entered . . . . . __ __/__ __/__ __
104. Certification number of data entry person . . . . . __ __ __ __ __

Final Follow-Up Visit Folder

k. Message for Diet K Patients

Will I be able to get ketoacids after the MDRD Final Follow-Up Visit?

Possibly, but not as you have during the MDRD Study. This is because ketoacids have not yet been approved by the Food and Drug Administration (FDA) for general medical use. The MDRD Study has had special approval from the FDA to give you ketoacids, and this authority ends at the Final Follow-Up Visit.

After that point, you may be able to get ketoacids through your own personal doctor or MDRD Study doctor. You would need to apply for special FDA approval based on your own health needs.

If you are interested, we encourage you to talk with your personal doctor and MDRD Study doctor. It is important to note that the ketoacids will not be free of charge after the Final Follow-Up Visit.

What if the study results show that Diet K slowed the loss of kidney function?

At that time, the FDA would consider approving ketoacids for general medical use. We don't know how long the approval process would take.

Will I need to change my eating pattern when I stop taking the ketoacids?

The MDRD Study dietitian will talk with you about any changes you may need to make in your eating pattern. The dietitian will also help you set nutrition goals and plan ways to reach those goals.

Please let us know if you have any other questions.

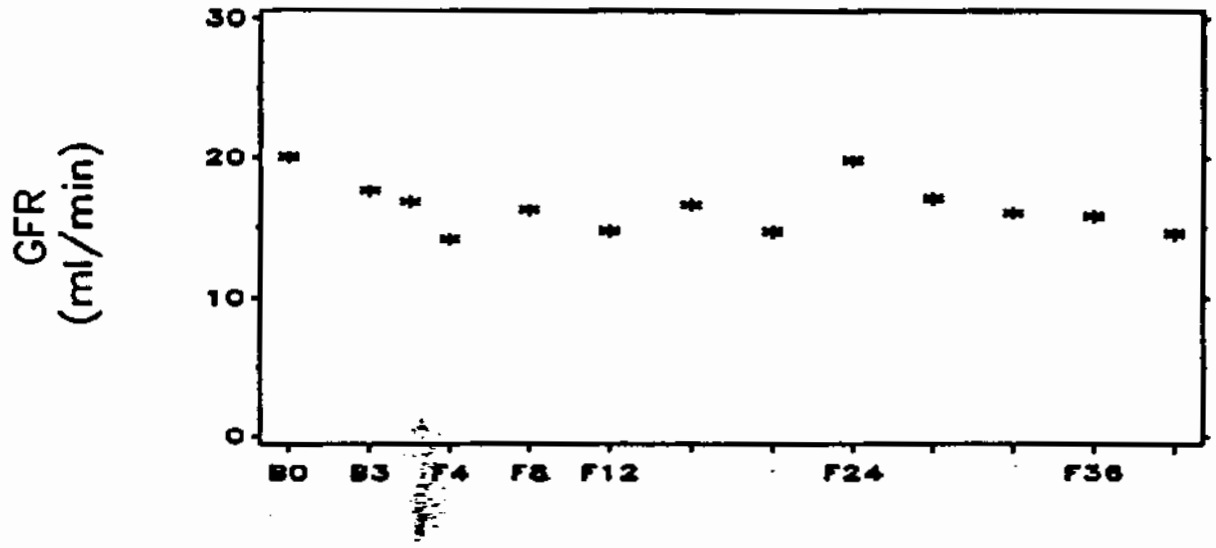
Appendix 4
Personal Results Visit Folder

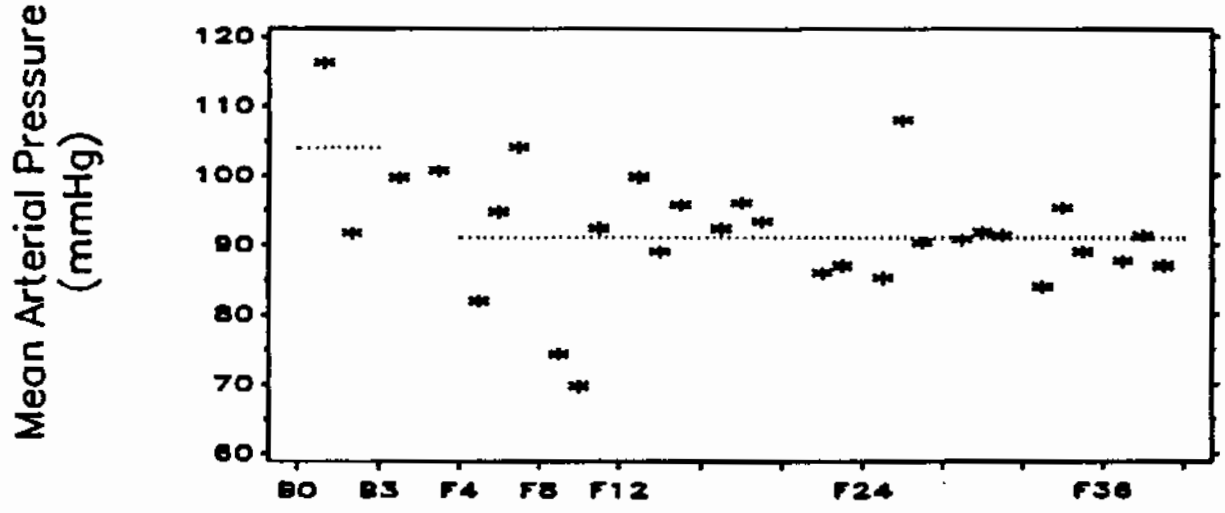
The Personal Results Folder is described in Section 4.3.

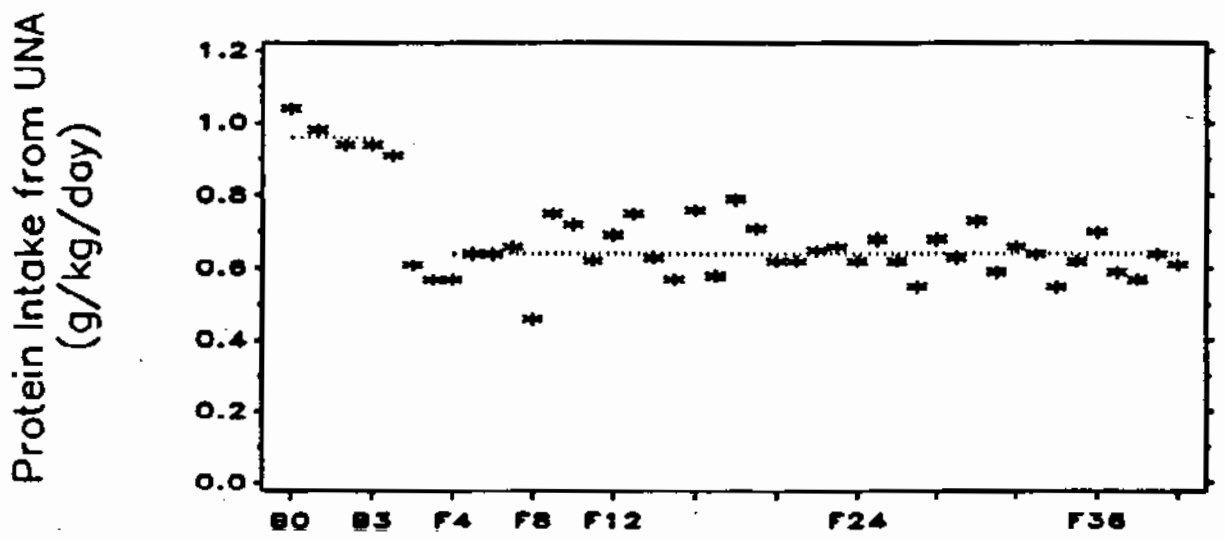
Table of Contents

Personal Results Visit Folder
a. GFR, MAP, and EPI

Data over Time for Patient





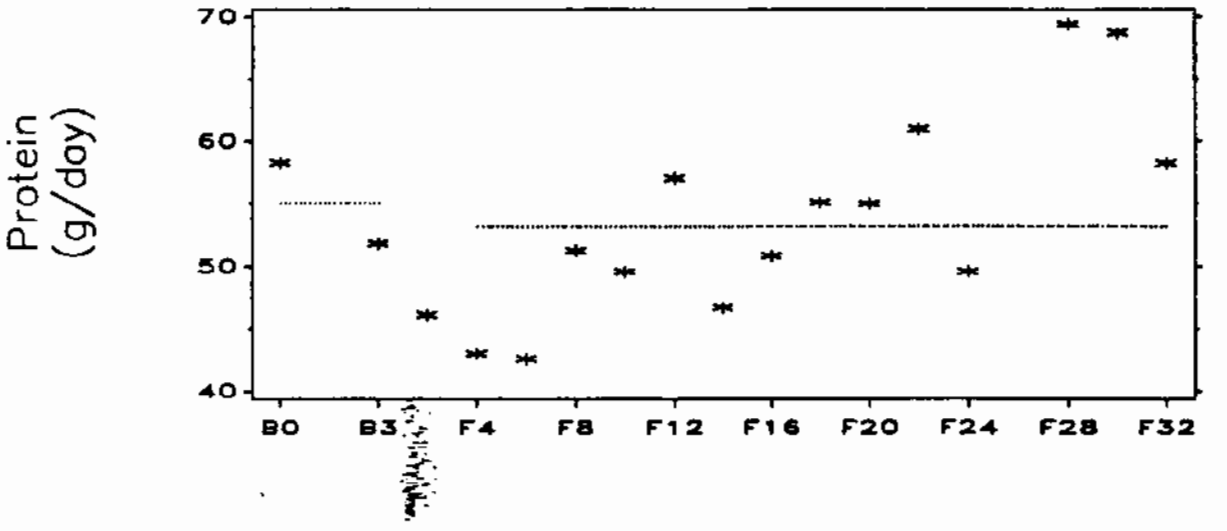


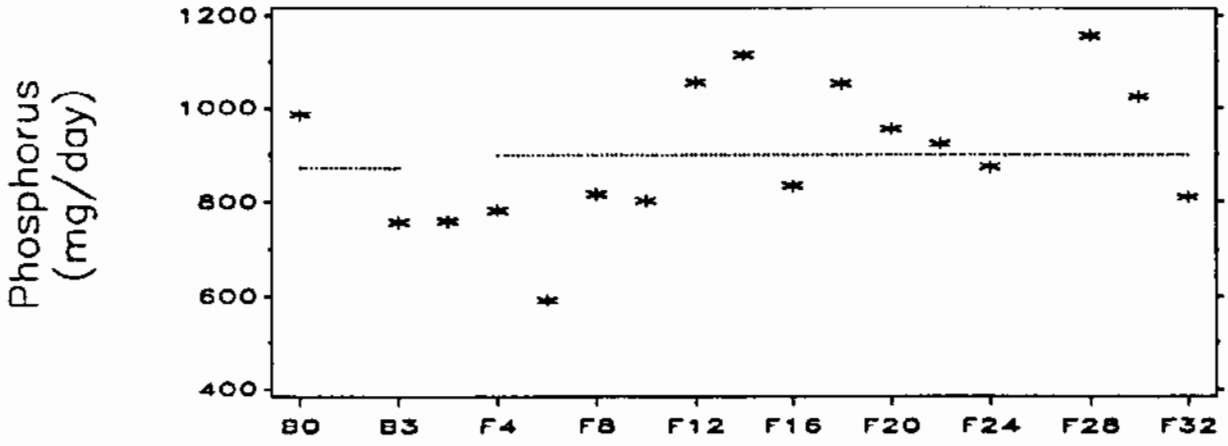
Personal Results Visit Folder

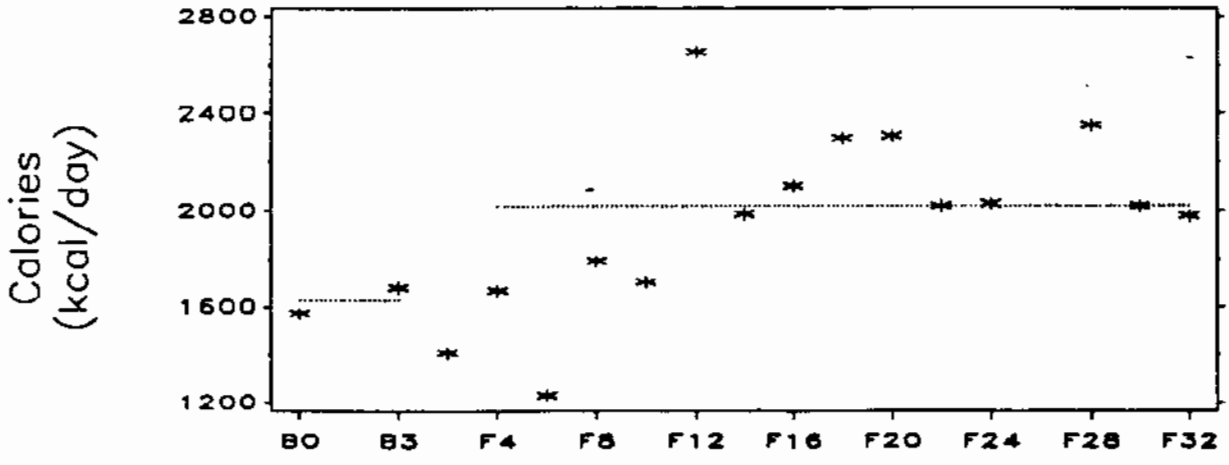
b. Protein, Phosphorus, and Calories

Dietary Data from 3-Day Food Records

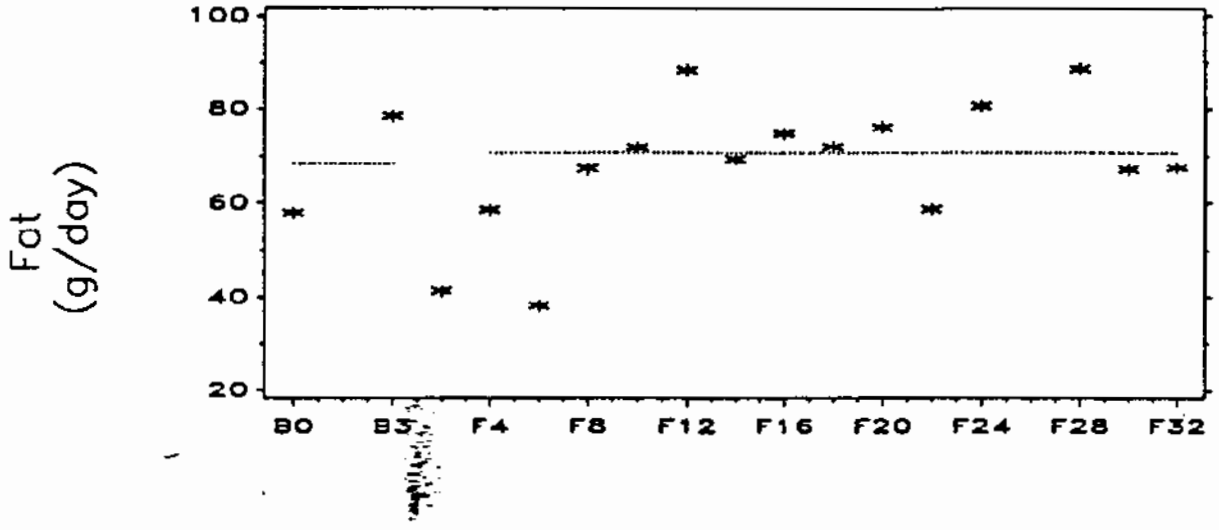
Patient

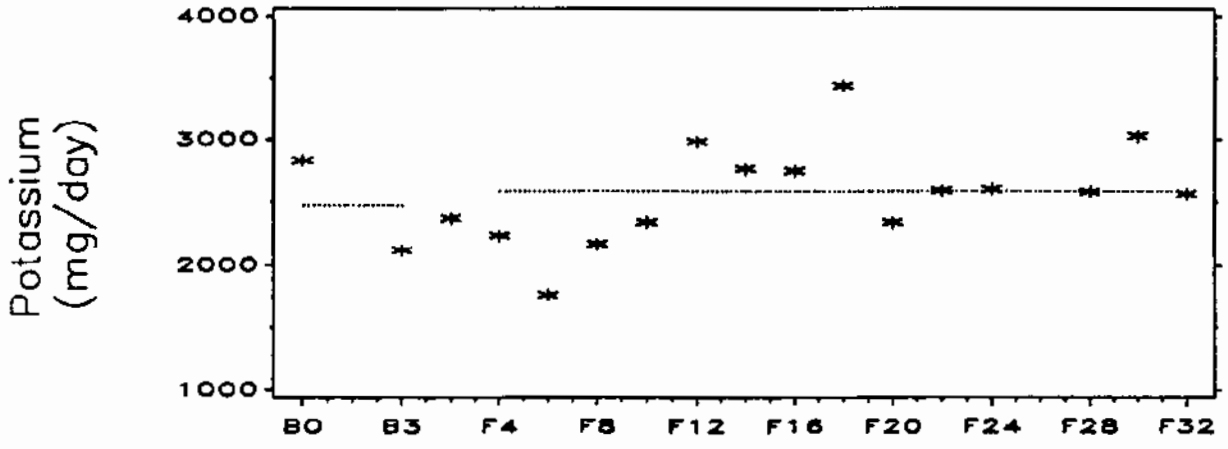


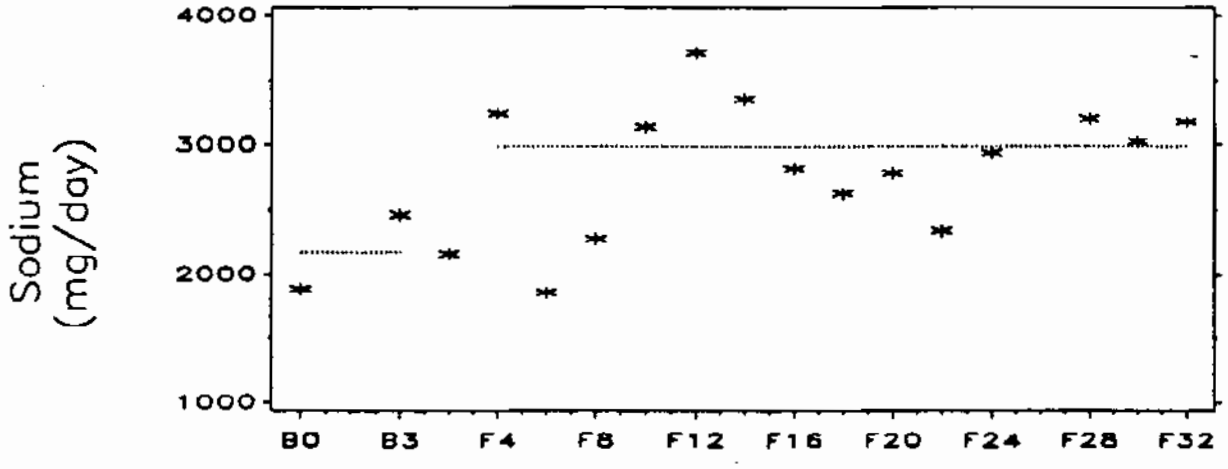




Dietary Data from 3–Day Food Records
Patient







Personal Results Visit Folder

d. Second Thank You Letter to Referring Physicians

Note: This letter must be personalized at each center and placed in the folder at each center.

Dear Dr. _____:

Your patient,_____, has had his/her first Post Close Out Visit for the MDRD Study. Enclosed are copies of information provided to your patient about his or her personal results. The estimated protein intake (EPI), glomerular filtration rate (GFR), and mean arterial pressure (MAP) results over the course of the study for your patient are provided in graphic form. Also enclosed is the biochemistry flowsheet on your patient for the MDRD Study period.

Mr/Ms._____ was randomized to a Diet K, L, M (0.28, 0.575, 1.3 gms protein/kg/day) and an MAP goal of _____mmHg. As you can see, your patent was at about ___% of their diet goal and ____% of the MAP goal. This indicates (poor, fair, good, excellent) compliance with the study diet and blood pressure regimen.

It is our recommendation that Mr./Ms._____ follow a diet of _____ gms/protein/kg/day and aim for a MAP goal (~BP /) pending the final results of the study.

Enclosed is a description of a Phase V Study we recommend for your patient. Your encouragement of patient participation in this ongoing study is deeply appreciated.

We will provide the overall MDRD Study results to you following Mr./Ms. _____'s Second Post Close Out Visit which is scheduled for approximately three months from now.

Sincerely,

_____,M.D.

for the MDRD Study

e. **How has the MDRD Study helped me?**

How have I made a difference?

P/All/16/9-92

Personal Results Visit Folder

f. Nutrition Prescription Form

For _____ Date _____

Protein _____ grams/day

Phosphorus _____ milligrams/day

Calories _____ to _____ kilocalories/day

Sodium _____ to _____ milligrams/day

Multi-vitamins _____ tablets/day _____

Calcium _____ mg/day _____

Iron _____ mg/day _____

Other_____

_____

_____

_____

_____

_____

_____

_____

_____ _____

g. Detailed Description of Phase V Study 1

Objectives for Study 1, A Study of Patients Who Have Not Progressed to Renal Failure

The objectives of Study 1 partially depend on the major results of Phase III, which are not known at this time. Based on two possible outcomes of Phase III, two overlapping sets of objectives are proposed. Regardless of the objectives of Phase V Study 1, the same Phase V Study 1 Protocol will be followed.

Objectives whether or not Phase III reveals any intervention to be superior

If the results of Phase III do not reveal that one diet or blood pressure goal is superior to any other, then it would be desirable to continue follow-up of all patients with conventional diet and blood pressure goals, and with a less intensive schedule of visits and measurements.

Objectives of Study 1 which are not dependent on the superiority of one diet or blood pressure goal are listed below. For all patients, the objectives are to investigate the relationships among a number of variables relating to diet, blood pressure, nutritional status, renal function, and progression of renal disease. Although these relationships will be explored using the Phase III data, the longer duration of follow-up and the further progression of renal disease during Phase V will in some cases increase the power of these analyses. The analyses include, but are not limited to the following (note: these analyses are listed in order of priority):

a) Validation of the use of the rate of decline in GFR as an end point. The objectives are to determine the pattern of decline in GFR over a longer interval, and whether the rate of decline in GFR is associated with the occurrence of renal failure, death, hospitalization and other measures of morbidity.

Analysis plan: Analyses with occurrence of renal failure, death, hospitalization and other measures

of morbidity as the outcome, with baseline GFR and GFR slope as the predictor variables.

b) Assessment of risk factors for progression of renal disease. Based on the rate of decline in GFR, "fast" and "slow" progressors will be defined and compared for a number of characteristics, including (but not limited to) actual dietary intake, nutritional status, blood pressure, anti-hypertensive drug regimen, renal diagnoses, other medical diagnoses, psychosocial characteristics, and quality of life.

Analysis plan: Analyses with GFR slope as a continuous outcome and as a categorical outcome (fast or slow) and the above characteristics as the predictor variables.

c) Evolution of malnutrition in renal failure. The objectives are to determine, in patients with progressive loss of renal function, the influence of dietary intake and renal function on the evolution of abnormalities in nutritional status that commonly accompany the progression of renal disease and development of uremia.

Analysis plan: Analyses with measures of nutritional status as outcomes and level of GFR and actual dietary intake as the predictor variables.

d) Effect of nutrition on morbidity prior to onset of renal failure. The objectives are to determine the influence of nutritional status on morbidity, assessed primarily from hospitalizations.

Analysis plan: Analyses with days of hospitalization as the outcome and measures of nutritional status included among the predictor variables.

Objectives if Phase III reveals an intervention to be superior

If the results of Phase III reveal that one diet or blood pressure goal is superior to the other, then at the Study Results (Post Close Out #2) Visit, the patients will be given the results showing which diet or blood pressure goal is superior and how effective that intervention has been shown to be. If either blood pressure goal is shown to be more effective, we will show the patient the observed advantage of that

blood pressure goal and, if appropriate for the patient, advise that he or she follow that blood pressure goal. If Diet L or Diet M is shown to be more effective, we will show the patient the observed advantage of that dietary goal and, if appropriate for the patient, advise that he or she follow that diet. If Diet K is shown to be more effective, we will show the patient the observed advantage of that dietary goal and, if appropriate for the patient, advise that he or she follow Diet L for the time being, until keto acids are approved by the FDA, and then follow Diet K in the future.

Patients who do not wish to follow the intervention revealed to be superior are still eligible for Phase V.

In this scenario, objectives a to d previously listed would still apply. Two additional objectives to further study under this outcome would be as follows:

e) For patients already assigned to the superior diet or blood pressure goal, the objectives are to determine the effectiveness, safety and compliance to these regimens when patients are followed for an even longer duration and with a less intensive schedule of visits and measurements.

Analysis plan: Comparison of GFR slope, nutritional status, dietary intake, and blood pressure between Phases III and V.

f) For patients who had not already been assigned to the superior diet or blood pressure goal and who change to the superior diet or blood pressure goal, the objectives will be to determine the effect of changing from one prescription to another on the rate of decline in GFR and nutritional status, and to determine if compliance to diet and blood pressure goals with a less intensive schedule of visits is as complete as observed during Phase III.

Analysis plan: Compare changes in GFR slope, nutritional status, dietary intake and blood pressure between Phases III and V, relating these to changes in dietary goals and blood pressure goals.

Protocol for Study 1

Eligibility criteria: All patients in Study A and Study B who have not reached renal failure, as defined by initiation of long-term dialysis or transplantation or who remain on dialysis; and who consent to enter Phase V.

Follow-Up (see Table 1): At initial and conclusion: Every four months and at conclusion: diet prescription, 3-day food records, 24-hour urine, blood pressure measurements, medications, serum proteins, lipids, and other chemistries, anthropometry, record of hospitalizations. Quality of life interview at conclusion. Follow-up terminates at time of onset of renal failure.

Start Date: Starting on April 1, 1993 and ending on June 15, 1993, or expiration of the May-June isotope

Starting April 1, 1994, or on the date of the receipt of the March-April isotope, and

End Date: Ending on May 30, 1994.

Table 1
Phase V, Study 1 Visits and Measures

For each patient: Phase V begins at Post Close Out #2 (April 1 to June 15, 1993).
Phase V ends on May 31, 1994.

Visit Name:	**"Post Close Out Visit #2"**	**Follow-Up**	**Follow-Up**	**Conclusion**
Phase V Visit Month	**0**	**4**	**8**	**11, 12, or 13**
GFR	X			X
24-hour Urine EPI Other measures	X	X	X	X
Blood Tests: Serum albumin Serum transferrin Lipid profile Other measures	X	X	X	X
Diet Prescription	X	X	X	X
3-Day Diet Diary	X	X	X	X
Anthropometry	X	X	X	X
Medication Record	X	X	X	X
RZ Blood Pressure	X	X	X	X
QWB Interview	X			X
Hospitalizations	X	X	X	X

(Dialysis, transplants, and deaths will be recorded as needed.)

FREQUENCY AND LOCATION OF FOLLOW-UP LABORATORY TESTING IN PHASE V

	Post Close Out II (Baseline)	4 Months	8 Months	End
Glucose	L	L	L	L
Sodium	L	L	L	L
Chloride	L	L	L	L
Potassium	L	L	L	L
Bicarbonate	L	L	L	L
CBC WBC, Hgb, Hct	L	L	L	L
Differential*	L			L
Iron	L			L
Magnesium	L			L
Phosphorus	C	C	C	C
Calcium	L	L	L	L
SUN	C	C	C	C
Creatinine	C	C	C	C
Albumin	C	C	C	C
Transferrin	C	C	C	C
Standard Lipid Profile: Total, HDL, LDL Cholesterol, Triglycerides	C			C
Complete Lipid Profile: HDL2, HDL3, Apoliproteins A1 and B	C			C
Plasma "After Thought"				C
24 Hr Urine	C	C	C	C
Protein	C	C	C	C
Urea Nitrogen	C	C	C	C
Creatinine	C	C	C	C
Phosphorus	C	C	C	C
Sodium	C	C	C	C
Potassium	C	C	C	C
Urine "After Thought"				C

Personal Results Visit Folder

h. Informed Consent for Phase V

Each patients Personal Results Visit Folder will include the informed consent form for Phase V Study 1 which was approved by that Center's IRB. The Clinical Center staff members will put these in the folders.

An example informed consent form for Phase V Study will be written by the Executive Committee in October and distributed to the centers on or before November 1, so that there is time to have it approved before the end of 1992.

Appendix 5

The Study Results Visit Folder

Table of Contents

Study Results Visit Folder

a. MDRD Study Results Report

This report will be prepared by the Executive Committee and approved by the Steering Committee prior to the March 9, 1993 Steering Committee Meeting.

b. Study Results Letters to Referring Physicians

The letters will be like this:

> Dear MDRD Referring Physician:
>
> We are pleased to enclose the study-wide results for the MDRD Study. The contribution made by the patients you referred to the MDRD Study has been enormous. Please feel free to call me if you have any questions.
>
> Sincerely,
>
> XXXXXXXXX

c. Informed Consent for Phase V

See item g in the previous appendix for the Personal Results Visit Folder.

d. List of Local Registered Dietitians

Prior to April 1, 1993, each center must prepare a list of local registered dietitians to include in the Study Results Visits Folder prior to the patients' arrival at the Study Results Visit.

e. How Has the MDRD Study Helped Me?

(See item d in the previous appendix for the Personal Results Visit.)

f. Nutrition Prescription Form

(See item f in the appendix for the Final Follow-Up Visit Folder.)

g. "Keeping Track" Booklets or "Personal Protein Counters"

At each center, the study team may place the usual MDRD "Keeping Track" booklet or "Personal Protein Counters" in the Study Results Visits Folder.

h. Order Forms

Each center can place a new Special Food Products Order Form (to be developed), in the folder for any patient who uses special food products.

Appendix 6

Post Stop Point Study Results Folder

Table of Contents

Post Stop Point Study Results Folder

a. MDRD Study Results Report

This report will be prepared by the Executive Committee and approved by the Steering Committee prior to the March 9, 1993 Steering Committee Meeting.

b. Detailed Description of Phase V Study 2

Objectives for Study 2, A Study of Dialysis Patients

The objectives of Study 2 are to determine whether the dietary prescription, actual dietary intake, and nutritional status prior to the onset of replacement therapy (dialysis for renal failure) affect morbidity and mortality after the initiation of replacement therapy. Outcomes to be assessed include days of hospitalization within the first four months of initiating long-term dialysis, days of hospitalization annually, number of hospital admissions, causes of hospitalizations, and mortality.

Analysis plan: Comparison of days of hospitalization and causes of hospitalization among randomized groups. Analyses with days of hospitalization due to selected causes as the outcome and actual dietary intake, measures of nutritional status, and dialysis prescription as the predictor variables.

Protocol for Study 2

Eligibility criteria: Patients in Study A and Study B who reached renal failure and were treated by dialysis only or dialysis, either before the conclusion of Phase III and consent to enter Phase V.

Follow-Up (see Table 2): After four months and at conclusion; for all patients, diet prescription, 3-day food records, BP measurements, medications, serum proteins, lipids, and other chemistries, record of hospitalizations (non-access related and access related will be analyzed separately), anthropometry, and quality of life interview. Follow-up terminates at the time of death or transplantation. (Four month interval is chosen because this corresponds to the post stop point follow-up schedule for Phase III.)

For all patients, the Clinical Center staff will contact the patient's dialysis deliverer and try to arrange for dialysis data collection. If possible, the dialysis provider should agree to give dialysis delivery data over the phone. If this is not possible, the clinical center staff should

obtain permission to travel to the dialysis provider and transcribe the dialysis data from the patient records there. If neither of these is possible, the patient is still eligible for Study 2. The data quantifying the delivery of dialysis will be missing for that patient.

A new Hemodialysis Delivery Data Collection form (MDRD Form 55) will be used to collect data (for hemodialysis patients only) regarding type of dialyzer and membrane used, times on dialysis, dialysis prescription, and pre and post BUN. By the end of 1992, each Center that is participating in Phase V Study 2 must pilot test the Form 55 for two hemodialysis patients who are being dialyzed at two different sites and on one peritoneal dialysis patient.

Table 2

Phase V, Study 2 Visits and Measures (for patients who have reached renal failure)

For each patient: Phase V begins at Post Close Out #2 (April 1 to June 15, 1993). Phase V ends on May 31, 1994.

Visit Name:	"Post Close Out Visit #2"	Follow-Up	Conclusion
Phase V Visit Month	0	4	11, 12 or 13
Blood Tests: Serum albumin Serum transferrin Lipid profile Other measures	X	X	X
Diet Prescription	X	X	X
3-Day Diet Diary	X	X	X
Anthropometry	X	X	X
Medication Record	X	X	X
RZ Blood Pressure	X	X	X
QWB Interview	X	X	X
Hospitalizations	X	X	X
Dialysis Form 55 → done Retrospectively 3 times	X	X	X

Add Exec Cntct Number dropped

Post Stop Point Study Results Folder

c. Draft Dialysis Delivery Data Collection Form for MDRD Phase V Study 2

Obtain data for last dialysis session prior to visit by phone or by transcribing it from dialysis unit records. For hemodialysis patients, use data from a day on which pre and post dialysis BUN were measured. The form is completed once retrospectively for the first Post Stop Point Visit, once retrospectively at the next annual type visit and prospectively for the three Phase V visits.

1. I.D. . . . . __ __ __ __ __ __

2. Namecode . . . . . __ __ __ __

3. Clinic . . . . . __ __
   a. Visit Type . . . . . __
   b. Visit Number . . . . . __ __.__

For Either Type of Dialysis

4. a. Has residual renal function been measured in the past month? (1=yes, 2=no) __
   b. If yes, estimated GFR (ml/min) . . . . . __ __.__

5. a. Serum calcium date . . . . . __ __/__ __/__ __
   b. Serum calcium level . . . . . __ __.__ __

6. a. Serum phosphorus date . . . . . __ __/__ __/__ __
   b. Serum phosphorus level . . . . . __ __.__ __

7. a. PTH date . . . . . __ __/__ __/__ __
   b. PTH level . . . . . __ __.__ __

For Hemodialysis Patients

8. Date of dialysis session . . . . . __ __/__ __/__ __

9. Dialyzer type: 1=Parallel Plate, 2=Hollow Fiber . . . . . __

10. a. Manufacturer of dialyzer (20 characters)_____
    b. Number following manufacturer's name . . . . . __ __ __ __ __ __

11. a. Membrane type (see codes) . . . . . __ __
    b. Membrane surface (see codes) . . . . . __ __

12. Time dialysis began . . . . . __ __:__ __

13. Time dialysis ended . . . . . __ __:__ __

14. Blood pump speed (per minute) . . . . . __ __ __

15. Pre dialysis BUN . . . . . __ __.__ __
    Pre dialysis weight . . . . . __ __ __.__

16. Post Dialysis BUN . . . . . __ __.__ __
    Post dialysis weight . . . . . __ __ __.__

17. Dialysis Prescription
    a. Prescribed KT/V . . . . . __.__ __
    b. Prescribed urea reduction ratio . . . . . 0.__ __
    c. Prescribed TAC urea . . . . . __ __ __

18. How many times per week is the patient currently being dialyzed? . . . . . __

19. How long is each session prescribed to last (in minutes, i.e., 3 hrs.=180) __ __ __

20. a. Type of dialysate bath (1=acetate, 2=bicarbonate, 3=other) . . . . . __
    b. Calcium content in the bath . . . . . __.__ __
    c. Potassium content in the bath . . . . . __.__ __

For Peritoneal Dialysis Patients Only

21. Type of peritoneal dialysis (1=CAPD or 2=CCPD) . . . . . __

22. a. Dialysis prescription (liters/day of dialysis infused) . . . . . __ __ __ __
    b. Daily schedule/number of exchanges per day . . . . . __ __ __

23. BUN . . . . . __ __.__ __

24. PET (Peritoneal Equilibration Test) Result . . . . . __
    a. D/D_0 Glucose (2 hours) . . . . . __.__ __
    b. D/D_0 Glucose (4 hours) . . . . . __.__ __
    c. D/P Creatinine (2 hours) . . . . . __.__ __
    d. D/P Creatinine (4 hours) . . . . . __.__ __

25. Glucose concentration . . . . . __ __.__

For All Forms

101. Date this form completed . . . . . __ __/__ __/__ __

102. Certification number of person completing this form . . . . . __ __ __ __ __

103. Date this form entered . . . . . __ __/__ __/__ __

104. Certification number of person entering this form . . . . . __ __ __ __ __

Post Stop Point Study Results Folder

d. Informed Consent for Phase V Study 2

Each patients Post Stop Point Results Visit Folder will include the informed consent form for Phase V Study 1 which was approved by that Center's IRB. The Clinical Center staff members will put these in the folders.

An example informed consent form for Phase V Study will be written by the Executive Committee in October and distributed to the centers on or before November 1, so there is time to have it approved before the end of 1992.

Appendix 7

Study F Close Out

Table of Contents

Study F Close Out

a. Letter of Appreciation

An example letter of appreciation will be distributed by November 1 so it can be personalized for each Study F patient prior to the first Study F Close Out Visit on December 1.

b. Modification of Diet in Renal Disease Study
MDRD Study Survey for Non-Randomized Patients

Your honest thoughts and feelings about the MDRD Study are important to us. Your answers to this survey will help us learn what you liked and did not like about the MDRD Study. Your answers will also help us to better prepare for future studies. Please answer all of the questions, place your evaluation form in the envelope, and seal it. The sealed envelope will be sent unopened to the MDRD Data Coordinating Center in Cleveland, Ohio.

No one at your clinical center will see your answers to this survey. Your answers will be kept strictly confidential.

Please circle a Y for yes and N for no.

1. Thinking back, why did you decide to start in Baseline of the MDRD Study?

A. Free medical services.	Y	N
B. Close, frequent medical monitoring.	Y	N
C. Reassurance.	Y	N
D. Hope for physical improvement.	Y	N
E. To help others with kidney disease.	Y	N
F. To take part in research.	Y	N
G. My doctor recommended it.	Y	N
H. My family wanted me to be in the study.	Y	N
I. It seemed harmless.	Y	N
J. Curiosity - I wanted to give it a try.	Y	N
K. Had time available.	Y	N
L. Other (please state)_____		

Modification of Diet in Renal Disease Study
MDRD Study Survey for Non-Randomized Patients

2. Who do you feel was helped by the MDRD Study?

A. Myself	Y	N
B. Scientists	Y	N
C. The MDRD staff	Y	N
D. Other people with kidney disease	Y	N
E. My family members	Y	N
F. My friends	Y	N

G. Other (please state)_____

3. For patients who attended Study F Visits: Have any of the items below been a problem for you in the MDRD Study?

1 = Never
2 = Rarely
3 = Sometimes
4 = Often
5 = Always

1 2 3 4 5	A. Travel to and from the clinic
1 2 3 4 5	B. Parking
1 2 3 4 5	C. Location of clinic
1 2 3 4 5	D. Long waits for clinic visits
1 2 3 4 5	E. Hurried clinic visits
1 2 3 4 5	F. Too much time spent in clinic visits
1 2 3 4 5	G. Too many clinic visits
1 2 3 4 5	H. Inconvenient scheduling of visits
1 2 3 4 5	I. Changes in the staff at the MDRD Clinic
1 2 3 4 5	J. Work-related problems
1 2 3 4 5	K. Family problems related to my attending visits
1 2 3 4 5	L. Family problems related to following my eating pattern

Modification of Diet in Renal Disease Study
MDRD Study Survey for Non-Randomized Patients

4. The MDRD Study has placed a number of demands on you. Please rate the items below on a scale from 1 to 5 where:

1 = NOT at all unpleasant or difficult;
5 = EXTREMELY unpleasant or difficult.

1 2 3 4 5 A. Baseline GFR

1 2 3 4 5 B. Baseline blood tests

1 2 3 4 5 C. Baseline 24-hour urine collection

1 2 3 4 5 D. Baseline three-day food records

1 2 3 4 5 E. Study F phone calls to me

1 2 3 4 5 F. Study F phone calls to my physician

5. For each statement below, please show how much you agree or disagree on a scale from 1 to 5 where:

1 = Strongly Agree
2 = Agree Somewhat
3 = Undecided
4 = Disagree Somewhat
5 = Strongly Disagree

1 2 3 4 5 A. My decision to take part in the MDRD Study was a good idea.

1 2 3 4 5 B. The results of the MDRD Study will be of great value to people with kidney disease.

6. Date form completed __ __/__ __/__ __

Please feel free to write any other comments on the back of this form. These comments will be read and summarized confidentially by the people who work at the MDRD Data Coordinating Center at The Cleveland Clinic Foundation. Your comments will not be shown to any of the staff members at your MDRD clinic.