

**Modification of Diet in Renal Disease Study
STOP POINT FORM**

This form must be completed by the study coordinator and/or physician when a stop point has been reached. Refer to section 13 of the Protocol for a detailed review of each stop point. The Review Committee should be contacted to confirm that a stop point has been reached prior to completing this form.

QUESTION # INSTRUCTIONS

4. Enter the code associated with the Study which the patient has been part of until the time the stop point occurred.
5. Enter the code associated with the Diet which the patient has been on.
6. Enter the date that the stop point was declared.

Item 6 on the Stop Point Form is the date the stop point is declared. Generally speaking, this will be the day that the team at your clinic decides that, yes, this person needs to be on dialysis as soon as possible. So, you file the Form 11, enter the "date the stop point is declared", and, if the patient actually starts dialysis before you file the form, you can enter "date dialysis began" for item 12b. (If you do not yet know the date the dialysis began, you can get this to us later in 11b. on a future Form 12 for an abbreviated, post stop point visit.)

The reason for this reminder is the P1 visit. Recall that the Protocol requires a special post stop point (P1) visit within two weeks of the stop point being declared. This should, of course, be held as soon as possible after the stop point. But, if you were to use the date of dialysis as the date the stop point is declared, and if that date is several weeks in the past, you would already be outside the window of the P1 visit. Those P1 data are important. Using the date your team was aware of the stop point will guarantee you have time for the post stop point visit.

7. If the patient is not in Study A, item 7 is blank. It will be skipped on the data entry screen.
 - a. Enter yes if the GFR is <50% of the Baseline 3 GFR or if the GFR has fallen to ≤ 20 ml/min/1.72m². The DCC will provide this information in a report if it occurs.
 - b. If the patient was part of Study A and reached ONLY a renal function stop point, the patient is now eligible for Study C. Review informed consent and complete Form #31 if patient will continue in Study C.

Items 8-13 should reflect the primary reason a stop point is being declared. Only one of these items should reflect a positive response.

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- | <u>QUESTION #</u> | <u>INSTRUCTIONS</u> |
|-------------------|--|
| 8. | Enter a 1 if serum albumin has been <3.0 g/dl on two successive monthly determinations after the energy and protein prescriptions have been altered to improve serum albumin. (Note that low serum albumin due to intercurrent illness does not comprise a stop point.) Enter a 2 if serum albumin is >3.0 g/dl. |
| 9. | Enter a 1 if there has been weight loss resulting in a body weight $<75\%$ of the patient's standard body weight (SBW) despite an increase in the patient's energy intake. Enter a 2 if body weight is $>75\%$ SBW. |
| 10. | Enter a 1 if serum phosphorus ≥ 6.0 mg/dl for four consecutive months despite: 1) review of dietary phosphorus and further restriction where possible; 2) addition of aluminum phosphate binders; and 3) measurement of serum inorganic phosphate with the patient fasting overnight. Enter a 2 if serum phosphorus is <6.0 mg/dl. |
| 11. | Enter a 1 if the patient has developed acute renal failure.
Enter a 2 if a serious medical condition has occurred (outlined in detail previously in the instructions for the Screening Form). Enter the name of this medical condition (in the space provided).
Enter a 3 if there is no serious medical condition that would be considered the primary reason for a stop point. |
| | If a patient is going on dialysis, item 11 should be 3, no, and item 12 completed. |
| 12. | Enter a 1 if patient will go on dialysis. Enter the date of the first dialysis if it has already occurred. Enter the type of dialysis. Enter a 2 if dialysis is not applicable. |
| 13. | Enter a 1 if the patient will have transplant. Enter the date of transplantation if it has already occurred. Enter a 2 if the patient will not be transplanted. |
| 14. | Enter yes or no for each of the diets prescribed for the patient now that a stop point has been reached. |
| 15. | Enter a 1 if the patient's medical regimen will change with regard to anything other than diet, medications, dialysis or transplantation as described above. Please specify. |

MDRD

Modification of Diet in Renal Disease Study Stop Point Form

This form is to be completed when a stop point has been reached. The Clinical Management Committee should be contacted prior to completing this form.

FORM # 1 1

1. Patient Identification Number.....
2. Patient Name Code.....
3. Clinical Center.....
4. Study (1 = A, 2 = B, 3 = C).....
5. Diet.....
 1 = Diet K
 2 = Diet L
 3 = Diet M
6. Date stop point is declared...../...../.....

Note: Only one of items 7 to 13 can and should be answered yes in order for the patient to be at a stop point. The patient should not reach more than one stop.

7. a. Has the patient reached a GFR stop point? (Study A patients only.) (1 = yes, 2 = no) ..

The DCC will send a report.

A patient is eligible for Study C if the patient was in Study A and reached only a renal function stop point.

- b. Is this patient eligible for Study C? (1 = yes, 2 = no) ..

If yes, initiate Study C informed consent procedures. Complete Study C Assignment Form #31.

For All Study Patients

8. Is serum albumin still less than 3.0 g/dl after dietary intervention for the Low Serum Albumin Action Item? (Protocol, Section 13) (1 = yes, 2 = no) ..
9. Has body weight decreased to below 75% of standard body weight for 3 months after dietary intervention for the Weight Loss Action Item? (Protocol, Section 13) (1 = yes, 2 = no) ..
10. Has serum phosphorus been greater than or equal to 6.0 mg/dl on four consecutive monthly measurements after intervention for very high Serum Phosphorus Action Item? (Protocol, Section 13) (1 = yes, 2 = no) ..

Patient ID Number _____
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Form # 11
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- 101. Date this form completed..... ____/____/____
- 102. Certification number of person filling out this form..... _____
- 103. Physician's signature _____
- 104. Certification number of physician..... _____
- 105. Has form been signed by physician? (1 = yes, 2 = no)..... _____
- 106. Date form entered..... ____/____/____
- 107. Certification number of data entry person..... _____