

**Modification of Diet in Renal Disease Study
SAFETY VARIABLE REVIEW FORM**

This form is to be completed by members of the committee when they are reviewing a safety variable.

The original should be mailed to the DCC for key entry. The person taking primary responsibility for completing the form should keep a file copy.

For DCC Use Only
Rev. 5 3/27/90

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V ___
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**Modification of Diet in Renal Disease Study
Safety Variable Review Form
Clinical Management Committee**

This form is to be completed whenever a designated Clinical Management Committee member reviews a Clinical Management Committee safety variable. The original form should be sent to the DCC for key entry.

FORM # 3 8

- 1. Patient Identification Number.....
- 2. Patient Name Code.....
- 3. Clinical Center

For Questions 4 - 6, refer to the Visit Date, Visit Type, and Visit Number when the Safety Variable occurred

- 4. Date of Safety Variable Visit..... / /
- 5. Visit Type.....
- 6. Visit Number.....
- 7. Date of Safety Variable Review

Safety Variables Reviewed (Answer 1 = Yes, 2 = No)

- 8. Weight Loss Protocol Action Item #2.....
- 9. Persistent Symptoms of Low Blood Pressure Action Item #8.....
- 10. Declining Albumin Protocol Action Item #9.....
- 11. Low Albumin Protocol Action Item #10.....
- 12. Declining Transferrin Protocol Action Item #11.....
- 13. High Serum Potassium Action Item #21 if patient is on ACE.....
- 14. Hospitalization (as determined by the committee chairperson)

- 15. Result of review.....
 - 1 = More information is needed for assessment.
 - 2 = Appropriate response not yet implemented.
Committee chair should talk to involved P.I.
 - 3 = Appropriate response has been implemented. No action required.
 - 4 = Refer to external monitoring committee for unblinded review of individual record.

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101. Date this form completed..... _____/_____/_____

102. Certification numbers of committee members who completed this form _____

103. Date form entered..... _____/_____/_____

104. Certification number of data entry person _____

Retain a copy of this form for your files. Send the original to the MDRD Study Data Coordinating Center. Please use MDRD Study mailing labels:

MDRD Study Data Coordinating Center
Department of Biostatistics & Epidemiology
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195-5196
