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Clinical Center Evaluation Committee Chapter

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Manual of Operations Volume 3, Chapter 8
Clinical Center Evaluation Committee Chapter

Statement of Purpose. The purposes of the Clinical Center Evaluation Committee are: 1) to evaluate the performance of individual clinical centers; 2) to facilitate the development and operation of clinical centers by identifying problems and potential solutions; and 3) to respect the privacy and individuality of each center. The committee does not monitor the performance of the Data Coordinating or Nutrition Coordinating Centers.

Methods.

1. On-line monitors of the Data Coordinating Center and the Nutrition Coordinating Center:
   a. Monthly key variables
      1) recruitment activity
      2) attrition of patients and staff
      3) timeliness of visits
      4) timeliness of reporting
      5) quality of data and accuracy of data entry (overlap with Quality Control Committee)
   b. Comprehensive evaluation of data sent to the DCC and NCC (annual report developed in preparation for on-site visit). Data from key variables and elsewhere analyzed according to:
      1) team performance
      2) specific tasks e.g. data entry, GFR, diet counseling
      3) reported as absolute values, percent of expected, percentile rank relative to other new or established centers
      4) severity of deviations from expectations. (in the face of being able to monitor a mass of data, the Committee recognizes its responsibility to prioritized deviations).

2. Site visits (annual)

a. Assess adherence to protocol

b. Assess adequacy of support systems and environment

c. Evaluate organization, leadership and morale

d. Observe staff-patient contacts

3. Site-visit reports to PI's standardized outline

4. HCFA billing

Site visit teams will consist of 5-6 members; 1-2 Principal Investigators or Co-PI's (at least one of whom has experience on the Committee) and 1 each from NIH, HCFA, DCC and NCC. In terms of scheduling, a center will have at least one month advance notice and the major determinant of scheduling will be the availability of the Principal Investigator. The absence of other personnel will not necessarily preclude a site visit.

Accountability. The Clinical Center Monitoring Committee reports only to the Executive Committee of the Steering Committee. At the time that a site visit report is transmitted to the Executive Committee, a copy will be sent to the PI of the center that was visited.

MDRD

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.

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

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

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