

Volume 3, Chapter 7

Operations Committee Chapter

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Operations Committee Procedures:

- I. Committee charge as outlined in Phase III Protocol:
The Operations Committee assures that all study issues are appropriately dealt with in a timely manner. The committee monitors assignments to individual working committees and reviews the recommendations of the committees prior to presentation to the Steering Committee. The Working Committees in the MDRD Study are identified as the Clinical Management committee, the Quality Control Committee, the Compliance Committee, the Publications and Ancillary Studies Committee, the Clinical Center Evaluation Committee, and the Recruitment Committee. The membership of this committee includes the Chairman, who is also the Vice-Chairman of the Study, the Chairpersons of each of the Working Committees, a representative from the Data Coordinating Center and the Nutrition Coordinating Center, the HCFA Project Coordinator and the MDRD Program Director. The Chairman of the Steering Committee is an ex-officio member. This committee will meet approximately one month prior to each Steering Committee meeting. Meetings will be held via conference call.

- II. The Chairman is the Vice-Chairman of the Steering Committee. Committee membership includes chairman of other standing committees and representatives from DCC, NCC, NIH and HCFA. The MDRD Study Chairman is an ex-officio member.

- III. Work assignments originate from Study Chairman and Executive Committee. Communication is by way of the Operations Committee chairman or the DCC.

- IV. Coordination of committee assignments and communications flow:

- A. At Steering Committee meetings, work assignments are made by the Study Chairman or Operations Committee chairman.
 - B. In between Steering Committee meetings, work assignments are made by the Operations Committee chairman.
 - C. Standing committees meet between and during Steering Committee meetings.
 - D. Operations Committee meets approximately one month before meetings of the Steering Committee in order to review committee agendas prior to meetings at the Steering Committee. The Committee reviews and suggests items for the Steering Committee meeting agenda. In addition, the Committee considers any new issues that have arisen and suggests resolutions to be brought to the Steering Committee. Chairman reports to the Executive Committee on all items.
 - E. Further communication prior to the Steering Committee meeting occurs as necessary.
 - F. Committee reports are presented at Steering Committee meeting.
 - G. Further work assignments are made as above (A).
- V. Additional meetings may be necessary in order to carry out other assignments made by the Study Chairman or Executive Committee.