

CHAPTER 22 PROTOCOL CHANGES

22.1 General Principles

Version 1.0 of the HFM Study Protocol was finished on 9/21/09. This version was submitted to IRBs at the start of the study.

Protocol changes during the course of a study are not desirable and should not be made unless new information (from inside our outside the study) becomes available and strongly suggests that a change would strengthen the scientific validity of the study or protect the safety of study participants.

Recommendations for essential protocol changes may originate from the External Monitoring Committee, the Data Coordinating Center, or any one of the clinical centers or study committees.

Proposed changes will be submitted to the Steering Committee for consideration. The Steering Committee will decide whether the proposed modifications merit consideration and will determine the method of incorporating the proposed changes in the Protocol.

If a major change is considered, Steering Committee will receive a document showing the wording of the current protocol and the revised wording proposed.

There are nine voting members of the Steering Committee. These nine voting members are the six clinical center PI's, the DCC PI, the Steering Committee Chair, and the NIDDK Project Officer. A protocol change will be considered approved by the Steering Committee if two-thirds of the voting members are in favor of the change.

The Steering Committee Chair and the NIDDK Project Officer will judge whether a protocol change is considered major. If the Steering Committee approves what is considered to be a major change to the study protocol, this change will be presented to the External Monitoring Committee who will advise the NIDDK as to whether the Protocol change is advisable. The NIDDK may seek further advice from the external Advisory Committee or other experts outside of the HFM Study before making the final decision as to whether the recommended Protocol change is approved.

Corrections in numbering, paging, and format will be considered minor, non-essential changes, as will corrections of typographic errors. The DCC will keep track of the need for any non-essential changes needed and these changes will be made to the study protocol when an essential protocol change is needed.