



**Manual of Procedures (MOP)**  
**Section 1. Organization & Administration**  
**Appendix 1.2. Steering Committee Charter**

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## 1. OVERVIEW OF THE STEERING COMMITTEE

The D2d Steering Committee (SC) provides scientific leadership for the study. The committee works closely with its operational arm, the Executive Committee (EC), and the SC subcommittees, as described below. The SC is accountable to the primary study sponsor (NIDDK), via the EC.

## 2. MEMBERSHIP

### 2.1 Composition and Term

The SC consists of the following voting members:

- Chairperson (D2d study Principal Investigator).
- All other EC members (Two Vice-Chairpersons, Project Manager, Lead Statistician, Chairperson of the Research Coordinator subcommittee, NIDDK Project Scientist, NIDDK Program Official)
- Collaborating clinical site Principal Investigators.
- Central Laboratory Principal Investigator.

### 2.2 Nomination and Election

Membership to the SC is indefinite as long as the member continues to be actively involved in the D2d study in one of the roles listed above.

Administrative and other support staff, chairpersons and other members of the subcommittees who are managing specific areas of the protocol, other members of the Central Laboratory and study cores (e.g. Data Distribution Center), other representatives from the funding agency (NIH) may occasionally join the SC conference call, as needed.

## 3. DUTIES AND RESPONSIBILITIES

The committee's responsibilities include the following:

- Contributes to major scientific and programmatic decisions and implements changes as necessary to ensure the study is conducted according to the highest ethical standards, and as efficiently as possible.
- Reviews and amends the D2d study Protocol and Manual of Operations.
- Reviews all aspects of study conduct, advises and assists the Coordinating Center (CC) and EC on scientific, technical and operational matters.
- Works closely with its subcommittees, which are appointed by the EC.
- Reviews reports of study progress (e.g. recruitment).
- Reviews and approves decisions and recommendations by its subcommittees.

## 4. MEETINGS

The SC meets on a regular basis. Meetings are scheduled every month at the same day and time. If there are no active issues to discuss, scheduled meetings will be cancelled. If there is a need to meet

more often, additional meetings will be scheduled. Meetings are conducted via conference call. In-person meetings will occur during the annual D2d investigator meeting or at other times, if needed.

If unanimous consensus on major decisions cannot be reached, decisions will be made by majority vote. A quorum for holding an official vote requires voting by at least 70% of the membership. Voting can occur after the conclusion of a meeting as long as it takes place within the allotted time period. Each member of the SC has one vote. In the event of a tie, the Chair casts the deciding vote. Minutes will be recorded for each meeting and posted on the D2d web portal for viewing by the SC and will also be distributed to members via e-mail.