



Manual of Procedures (MOP)
Section 1. Study Organization, Administration and Governance
Appendix 1.1. Executive Committee Charter

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1. OVERVIEW OF THE EXECUTIVE COMMITTEE

The D2d Executive Committee (EC) acts as the operational arm of the Steering Committee (SC) and makes scientific, administrative and fiscal decisions, on behalf of the SC, for day-to-day operational issues requiring prompt action. The EC is accountable to the Steering Committee and the primary study sponsor (NIDDK).

2. MEMBERSHIP

2.1 Composition and Term

The EC consists of the following voting members:

- Chairperson (D2d study Principal Investigator)
- Two Vice-Chairpersons, appointed by the Chairperson
- Project Manager [CC representation]
- Lead statistician
- Chairperson of the Research Coordinator subcommittee
- NIDDK Project Scientist
- NIDDK Program Official

2.2 Nomination and Election

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

The process for removing and replacing an EC member is as follows:

- The Chair proposes removal of a non-NIDDK affiliated EC member. All other EC members need to vote unanimously for the removal to occur. The remaining EC members vote unanimously to elect a new member to take over the role of the member that was removed.
- The Chair can be removed from the committee or relieved from his responsibilities, if both NIDDK Project Scientist and Official concur. The remaining EC members vote unanimously to appoint a new Chair from the remaining EC membership or from outside the EC.
- The NIDDK Project Scientist and Project Official can only be removed and replaced by NIDDK.

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

3. DUTIES AND RESPONSIBILITIES

The committee's responsibilities include the following:

- Makes day-to-day 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 discusses all aspects of study conduct.
- Advises and assists the CC on technical and operational matters.
- Addresses problems or issues that arise between SC meetings.
- Develops agendas for the SC meetings.
- Reviews and selects collaborating clinical sites.
- Approves the removal of under-performing collaborating clinical sites.
- Communicates with the sponsor (NIDDK) and the DSMB (via the DSMB Executive Secretary)
- Establishes and disbands SC subcommittees, including appointment and removal of Chairs and Vice-Chairs.
- Appoints members of SC subcommittees and committees that fall under its jurisdiction (e.g. Clinical Outcomes Committee).
- Removes members of committees and SC subcommittees for the following reasons (non inclusive list): professional misconduct, misrepresenting the study, failure to disclose conflict of interest or other dishonorable research activities.
- Approves the appointment of a new site PI.

4. MEETINGS

The subcommittee meets weekly at the same day and time each week. Meetings are conducted via conference call. If there are no active issues to discuss, scheduled meetings will be cancelled. In-person meetings will occur during the annual D2d investigator meeting or at other times, if needed.

If a unanimous consensus on major decisions cannot be reached, decisions are made by majority vote. Each member of the EC 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 EC and will also be distributed to members via e-mail.