



Manual of Procedures (MOP)
Section 1. Organization & Administration
Appendix 1.3.6. Ancillary Studies Evaluation Subcommittee Charter

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1. OVERVIEW OF THE ANCILLARY STUDIES EVALUATION SUBCOMMITTEE

The D2d Ancillary Studies Evaluation subcommittee (ASES) develops and oversees the ancillary studies policies and procedures, evaluates ancillary study applications and monitors progress of approved ancillary studies. The ASES is accountable to the Steering Committee (SC).

2. MEMBERSHIP

2.1 Composition and Term

The ASES consists of members from the D2d Study Group (Executive Committee [EC], Coordinating Center [CC], collaborating clinical sites and Central Laboratory). The subcommittee is composed of D2d investigators with experience in a wide range of scientific disciplines, demonstrated commitment to the D2d study and deep understanding of its study design, interest in expanding the impact of the D2d study by serving in the ASES. To maintain continuity and efficiency, members are expected to serve, in general, a minimum of 2 years. Ad-hoc members may be appointed for less than 2 years, if there is a specific short-term need. The D2d Project Manager (or her designee) is a contributing member of the ASES and reviews publications and presentations, but does not vote to approve or disapprove submissions.

2.2 Nomination and Election

- At inception, the EC nominates members from the D2d Study Group to form the subcommittee. Nominees must have expressed interest and commitment in serving in the subcommittee.
- During the study, the EC may remove or replace subcommittee members.
- During the study, to replace members who step down or add members (e.g. augment the scientific expertise), the EC will solicit nominations for membership from the SC. The EC approves any new subcommittee members at its next scheduled meeting.

Administrative and other support staff, members of the Executive and Steering Committee, chairpersons of the subcommittees who are managing specific areas of the protocol, members of the Central Laboratory and other representatives from the funding agency (NIDDK) may occasionally join ASES conference calls, as needed.

2.3 Leadership

- The Chairperson(s) agrees to serve for a minimum of 2 years. The Chairperson is a member of the ASES and possesses qualifications that make her appropriate for the position, including: experience evaluating clinical research proposals, deep knowledge of the D2d study design and demonstrated leadership skills.
- The Vice Chairperson agrees to serve for a minimum of 2 years. The Vice Chairperson is a member of the ASES and possesses qualifications that make him appropriate for the position. The Vice Chairperson will act in the role of Chairperson, if the Chairperson is absent or if the Chairperson has a conflict of interest and needs to be excused from the review of an ancillary study.
- At inception, the EC appoints the subcommittee Chair and Vice Chair.

- During the study, the EC may replace the subcommittee Chair or Vice Chair. The EC solicits nominations for a new Chair or Vice Chair from the SC. The EC approves the new Chair or Vice Chair at its next scheduled meeting.

3. DUTIES AND RESPONSIBILITIES

The committee's responsibilities include the following:

- Develops, approves and oversees the ancillary studies policies and procedures, including development of the instructions for submission of proposals and accompanied documents (e.g. D2d Ancillary Study Application).
- Solicits ancillary study applications.
- Evaluates ancillary study letter of intents and applications and makes recommendations to the Steering Committee regarding the proposals.
- Monitors progress of approved ancillary studies.
- Seeks out guidance from other committees, as needed.

4. MEETINGS

The subcommittee meets monthly at the same day and time each month. Rarely, if there is an urgent need, additional meetings will be scheduled to accommodate ancillary study applications. In general, ancillary study applications (new or major revisions) are reviewed as soon as possible, but always within 90 days of submission. If there are no active issues to discuss, scheduled meetings will be cancelled. Meetings are conducted via conference call. In-person meetings will occur during the annual D2d investigator meeting or at other times, if needed.

If a unanimous consensus cannot be reached, decisions will be made by majority vote. A quorum for holding an official vote requires voting of 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 ASES has one vote with the exception of the D2d Project Manager (or her designee) who is a non-voting member. 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 ASES.