



Manual of Procedures (MOP)
Section 1. Organization & Administration
Appendix 1.3.7 Publications & Presentations Subcommittee Charter

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1. OVERVIEW OF THE PUBLICATIONS & PRESENTATIONS SUBCOMMITTEE

The D2d Publications and Presentations subcommittee (PPS) develops and oversees the policies and procedures by which D2d investigators will undertake analyses of D2d data and coordinates publications and presentations of study results. The PPS is accountable to the Steering Committee (SC).

The charges of the PPS are to:

- Encourage the development of high-quality peer-reviewed scientific manuscripts and presentations with broad participation by the D2d Research Group.
- Encourage the development of collaborations with investigators outside of the D2d Research Group who will conduct additional research to augment the core research goals and maximize the return on the investment in the D2d study.
- Preserve the scientific integrity of the D2d study in publications and presentations.
- Protect the rights and privacy of study participants in publications and presentations.

2. MEMBERSHIP

2.1 Composition and Term

The PPS 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 who have demonstrated a *commitment* to the D2d study, have *deep understanding of its methods*, and have successful publication and presentation records and experience in a range of scientific disciplines. 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.

⇒ It is important to understand that membership in the PPS neither entails co-authorship nor confers priority as a primary author in any publication and presentation that is derived from D2d and reviewed by PPS. Authorship will follow the guidelines presented in the Presentations and Publications policies and procedures document.

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 and chairpersons of the subcommittees who are managing specific areas of the protocol, members of the Central Laboratory, other representatives from the funding agency (NIDDK) may occasionally join the PPS conference call, as needed.

2.3 Leadership

- The Chairperson(s) agrees to serve for a minimum of 2 years. The Chairperson is a member of the PPS and possesses qualifications that make him/her appropriate for the position, including: commitment to D2d, deep knowledge of the D2d study design, strong publication record, knowledge of publication strategies and demonstrated leadership skills.
- The Vice Chairperson agrees to serve for a minimum of 2 years. The Vice Chairperson is a member of the PPS and possesses qualifications that make his/her appropriate for the position. The Vice Chairperson acts in the role of Chairperson if the Chairperson is absent or if the Chairperson has a conflict of interest.
- 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 Chairperson's responsibilities include the following:

- The Chair works with the PPS liaison from the Coordinating Center (CC) to determine the date, time, and place of meetings and prepare the agenda. The proposed agenda is distributed to the subcommittee by the CC liaison in advance of the meeting, together with any documents pertaining to the matters to be discussed.
- The Chair leads the subcommittee meetings, guides the subcommittee through the agenda items, and is deeply knowledgeable about all publication and presentation proposals and approved works in progress.
- The Chair works with the CC liaison to review, edit and approve the meeting's minutes, which the liaison distributes to the rest of the subcommittee, within 3 business days.
- The Chair works closely with the CC liaison to communicate with the lead author who submits proposals, manuscripts, and other information about ongoing data analyses.
- The Chair is occasionally invited to the EC meeting to inform the EC of current subcommittee issues and activities. This informal briefing serves as an opportunity for two-way communication between the subcommittee and the EC.
- The Chair also holds all responsibilities of a committee member.

The Vice-Chairperson's responsibilities include the following:

- Covers for the Chair when s/he is not available.
- Shares some of the responsibilities of the Chair.
- The Vice-Chair also holds all responsibilities of a committee member.

The committee's responsibilities include the following:

- Develops, approves, and oversees the policies and procedures for generation, review, and approval of all publications and presentations, including abstracts, for the core study and all ancillary studies.

- Ensures that the publications and presentations policies and procedures are followed fully at all stages of development (e.g. proposal prior to conducting analyses using D2d data, manuscript preparation prior to submission for external peer-review).
- Establishes a publication strategy, following equitable and transparent authorship guidelines, as described in the publications and presentations policy.
- Identifies publications and presentations to be prepared on behalf of the D2d Research Group and establish specific writing groups. Examples of such manuscripts include:
 - An overview of the D2d study design, as the first publication (shortly after study begins recruitment).
 - Baseline characteristics of the D2d study, as the second publication (shortly after enrollment is completed).
 - Publication(s) reporting the study's main outcome.
 - Additional publications reporting secondary outcomes.
- Reviews and approves all publications and presentations (including those from ancillary studies) that use D2d study data prior to submission for external peer review to ensure that:
 - o Publications are original and of high scientific merit and do not overlap with existing manuscripts (in preparation or published).
 - o Methodology description, data analyses and interpretation are appropriate and consistent with other D2d publications.
 - o Policies and procedures are followed, including authorship guidelines, so that authorship is equitable and proportional to investigators' efforts (see publications and presentations policy.).
- Reviews and approves the composition of writing groups.
- Provides feedback and guidance to the writing groups.
- Monitors progress of proposed analyses/manuscripts, especially in relation to the main study results, to ensure prompt completion and publication. If progress is insufficient, the PPS has the right to re-assign lead and senior authorship as needed to meet the communication goals of the study.
- Updates the SC on the status of all publications and presentations.
- Seeks guidance from other committees, as needed.

4. MEETINGS

The subcommittee meets on an as needed basis, in a timely fashion, to accommodate the review of publications and presentations. It is expected that the PPS will meet at least 3 times per year, and these meetings will be timed to coincide with major abstract deadlines for scientific meetings. In general, meetings will be conducted via conference call. In-person meetings may occur during the annual D2d investigator meeting or at other times, if needed.

Decisions will be made by majority vote. A quorum 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 PPS has one vote. Members who are authors of a publication or presentation will be recused from the discussion and the vote of such. 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 PPS and will also be distributed to members via e-mail.