**Data Safety and Monitoring Board Charter Template**

**Template Instructions**

Copy the text below in your own word processing software and replace the placeholder fields with your information.

**1. Introduction**

This Charter is for the Data and Safety Monitoring Board (DSMB) for the [**insert protocol title, or Network title**]

The Charter is intended to be a living document. The DSMB may wish to review it at regular intervals to determine whether any changes in procedure are needed.

**2. Responsibilities of the DSMB**

The DSMB is responsible for safeguarding the interests of study participants, assessing the safety and efficacy of study procedures, and for monitoring the overall conduct of the study [**or studies, in the case of a Network**].

The DSMB is an independent group advisory to the NIEHS, and is required to provide recommendations about starting, continuing, and stopping the study [**studies**]. In addition, the DSMB is asked to make recommendations, as appropriate, to the NIEHS about:

* Efficacy of the study intervention
* Benefit/risk ratio of procedures and participant burden
* Selection, recruitment, and retention of participants
* Adherence to protocol requirements
* Completeness, quality, and analysis of measurements
* Amendments to the study protocol and consent forms
* Performance of individual centers and core labs
* Participant safety, and
* Notification of and referral for abnormal findings

**3. Organization and Interactions**

The following [**separate diagram or description**] illustrates the relationship between the DSMB and other entities in this study [**Network**].

Communication with DSMB members will be primarily through the principal investigator (PI), NIEHS Program Office (for extramural studies), the appropriate Clinical Director (for intramural studies), and the Data Coordinating Center (DCC) if relevant. It is expected that other study [**Network**] investigators will not communicate with DSMB members about the study directly, except when making presentations or responding to questions at DSMB meetings or during conference calls.

**4. DSMB Members and NIEHS Program Staff**

DSMB members and their expertise are listed in Appendix A. NIEHS [**and other federal, if applicable**] Program Staff involved in the study, and their responsibilities are listed in Appendix B. Consistent with NIEHS policy, each DSMB will have a Chair and Executive Secretary (ES) proposed by the awardee institution (for extramural studies) or the CD (for intramural studies) and elected by the board members. The ES will provide an unbiased staff interface for the DSMB, especially during executive sessions. The ES is responsible for assuring the accuracy and timely transmission of the final recommendations and DSMB minutes.

**5. Scheduling, Timing, and Organization of Meetings**

DSMB meetings are usually held by remote connections. The purpose of the first meeting is to review and discuss this Charter, to provide an overview of study [**Network**] activities, to review and make recommendations about the protocol(s), and to determine the frequency of interim analyses and whether data will or will not be masked to identity of randomized groups. Enrollment in a study cannot begin until the DSMB’s Charter has been accepted by NIEHS, and IRB approval has been obtained at each site.

Meetings are usually held approximately twice a year, with additional meetings or conference calls scheduled as needed.

* For this DSMB, meetings and calls will be held: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* Review of interim data analyses will occur: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

The agenda for DSMB meetings and calls may be drafted by the DCC, or by the ES if no DCC exists, in consultation with NIEHS staff. The ES will finalize the agenda after consultation with the DSMB Chair. The agenda and meeting materials should be distributed by the DCC or ES \_\_\_\_\_\_week**[s]** before each meeting or call.

Before each meeting, when the agenda is sent out, the ES will ask all DSMB members to state whether they have developed any new conflicts of interest since the last formal annual report to NIEHS. If a new conflict is reported, the Chair and other members will determine if the conflict limits the ability of the DSMB member to participate in the discussion, and whether further evaluation of the conflict by the awardee institution for extramural studies, or the NIEHS ethics officer for intramural studies, is warranted. The DSMB also will review adverse event data, other safety data, enrollment data, and quality and completeness of study data at each meeting to ensure proper trial conduct. At intervals, as noted above, the DSMB will also review formal interim analyses of the primary end point.

It is expected that all DSMB members will attend every meeting and call. However, it is recognized that this may not always be possible. Quorum for voting is considered to be half the number of standing members plus one. The Board may wish to decide if particular expertise is needed within the quorum for the meeting to be valid. All standing Monitoring Board members are voting members. The Board may also wish to decide in advance whether *ad hoc* members can vote.

[**Complete as needed:** A quorum of this DSMB is considered to be:
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.]

**6. Discussion of Confidential Material**

DSMB meetings and calls will be organized into open, closed, and executive sessions.

* During the **open sessions**, information will be presented to the DSMB by the DCC, study investigators and NIEHS staff as appropriate, with time for discussion.
* During the **closed sessions**, the DSMB, DCC, and NIEHS staff, if appropriate and approved by the Chair, will discuss confidential data from the study [**studies**], including information on efficacy and safety by treatment arm. The DSMB will decide whether to remain masked to the treatment assignments at each meeting.
* The DSMB may elect to hold an **executive session** in which generally only the DSMB members and Executive Secretary are present in order to discuss study issues independently.

Voting on recommendations will follow Roberts’ Rules of Order (**Robert's Rules of Order Newly Revised (10th Edition) RONR** by Henry M. Robert III, William J. Evans (Editor), Daniel H. Honemann (Editor), Thomas J. Balch (Editor), Sarah Corbin Robert, Henry M. Robert III, General Henry M. Robert).

If the **closed or executive session** occurs on a conference call or video connection, steps will be taken to ensure that only the appropriate participants are on the call, and to invite others to re-join the call only at the conclusion of the executive session.

At the conclusion of the **closed or executive** sessions, the participants will be re-convened so that the DSMB Chair can provide a summary of the DSMB’s recommendations. This provides an opportunity for study investigators, the DCC, and NIEHS staff to ask questions to clarify the recommendations. The meeting is then adjourned.

**7. Reports of DSMB Deliberations**

* Formal minutes: The ES is responsible for the accuracy and transmission of the formal DSMB minutes. These minutes are prepared to summarize the key points of the discussion and debate, requests for additional information, response of the investigators to previous recommendations, and the recommendations from the current meeting. If concerns are identified, the report will outline the concerns, the board’s discussion of the concerns, and the basis for any recommendations that the DSMB has made in response to the concerns.
* The DSMB Chair may sign the minutes or indicate approval electronically via email. If there are no concerns or major issues raised, signed minutes will be sent to the NIEHS Program Office (for extramural studies) or Clinical Director (for intramural studies), the DCC if relevant, and the PI within \_\_\_\_\_ days of each meeting or call. If concerns or major issues are raised during the meeting, signed minutes will be sent to the NIEHS Program Office (for extramural studies) or Clinical Director (for intramural studies), the DCC, and PI within \_\_\_ days of the meeting or call. The PI will forward the minutes to appropriate AIs and IRBs as soon as possible. Subsequently, minutes are included in the materials for the subsequent DSMB meeting to be approved by voice vote at that meeting. Once they have been voted and approved by the Board, they are considered final.

**8. Reports to the DSMB**

For each meeting, the DCC, with input from NIEHS staff if needed, will prepare summary reports and tables to facilitate the oversight role of the DSMB. The DSMB should discuss at the first or subsequent meetings what data they wish to review and how it should be presented.

**9. Statistical Monitoring Guidelines**

At the first meeting, review of the protocol will include review of the statistical analysis plan. The DSMB should discuss the adequacy of that plan. The final plan, whether part of a research protocol or separate document, will be maintained as Appendix C to this charter. The DSMB should discuss the statistical monitoring procedures they propose to follow to guide their recommendations about termination or continuation of the trial. These procedures could include guidelines for early termination for benefit, termination for futility, and termination for safety reasons.

**Appendix A** - DSMB members and their expertise

**Appendix B** - NIEHS [and other federal, if applicable] staff involved in the study, and their responsibilities

**Appendix C** - Statistical analysis plan