

NOTE: See NIH website for data safety guidelines and templates per Institute:
<https://grants.nih.gov/policy/humansubjects/policies-and-regulations/data-safety.htm>

[INSTITUTION]

[Name of Study]

Funded by [Sponsor (grant number)]

Data Safety and Monitoring Board (DSMB) Charter

[Date]

Project Summary: [Insert project summary info from grant]

Aims: [Insert aims from grant]

Sites: [Name partnering communities here...]

Participants:

Inclusion criteria:

Recruitment Timeline:

[Insert information on intervention and waitlist groups (if applicable)]

Evaluation Measures: [Include data collection timepoints, what data is being collected]

DSMB Overview: The membership of the DSMB will include at least [list number of members and areas of expertise] (*Example: one diabetes care expert, one individual with expertise doing community-based participatory research with Tribal communities, and one biostatistician.*) DSMB members will not have direct involvement in the conduct of the study or financial, professional, or other Conflicts of Interest that would preclude them from participation. Potential members to be included on the DSMB will be shared with the program official for approval prior to invitation.

The primary responsibilities of the DSMB are to:

- 1) periodically review and evaluate the study data for participant safety, study progress, and, when appropriate, efficacy, and
 - 2) make recommendations concerning the continuation, modification, or termination of the trial.
- The DSMB is responsible for maintaining the confidentiality of its internal discussions and activities as well as project reports. The DSMB will review study protocol prior to implementation. During the trial, the DSMB will review cumulative study data to evaluate safety, study conduct, and scientific validity and integrity of the trial. DSMB members will receive timely, complete, and accurate data sufficient for evaluation of the safety of study participants. DSMB frequency of meetings will depend upon the rate of study enrollment, safety issues, data

availability, and interim analyses. The study coordinator will take minutes for DSMB meetings for board approval.

Specific Responsibilities of the DSMB: The specific responsibilities of the DSMB are listed below: Generally, the first responsibility of the DSMB will be to approve the final protocol of the clinical study named above, or the study/studies being undertaken by the research network named above so that the study/studies can begin enrolling patients. After initial approval, and at periodic intervals during the course of the study, the DSMB responsibilities are to:

- Provide input to assist the investigator(s) in protecting the safety of the study participants; Provide input to the investigator(s) on major changes to the research protocol, informed consent documents, and plans for data and safety monitoring;
- Review study performance, assist in the resolution of problems reported by the Principal Investigator (PI), provide input to the investigator(s) on the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the study sites, and other factors that may affect study outcomes;
- Review areas of concern regarding the performance of individual sites and provide comment to the investigator(s) on actions to be considered regarding sites that perform unsatisfactorily;
- Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study;
- Provide input to the investigator(s) on modification of the study protocol or possible early termination of the study because of attainment of study objectives, safety concerns, low likelihood of showing a benefit of the intervention, or inadequate performance (such as enrollment and retention problems);
- Determine trial stopping rules and review interim analyses in accordance with stopping rules.
- Make recommendations to [Sponsor] and the PI concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the intervention.
- Ensure the confidentiality of the study data.
- Comment on any problems with study conduct, enrollment, sample size and/or data collection.

Specific Responsibilities of the Investigator Team: The specific responsibilities of the investigator team, with regard to DSMB activities, are listed below.

- Schedule, coordinate, and host DSMB meetings.
- Prepare summary minutes for each DSMB meeting and maintain all meeting records.
- Prepare and provide materials and data to be reviewed by the DSMB, including:
 - A report on study progress, data collection and analysis, results as available, and a summary of adverse event data (blinded). The report will be emailed to the DSMB at least five working days prior to each meeting.
 - Other reports with unblinded adverse event data (SAE and AE). The report will be emailed to the DSMB at least five working days prior to each meeting.
 - Ad hoc data summaries or study documents as requested by the DSMB.

DSMB Members: The membership of the DSMB will consist of a maximum of four members and will include at least [list members and areas of expertise again here]. DSMB members will not have direct involvement in the conduct of the study or financial, professional, or other Conflicts of Interest that would preclude them from participation.

Meeting Schedule: The frequency of DSMB meetings will depend upon the rate of study enrollment, safety issues, data availability, and interim analyses. The meeting will be hosted by the Investigator team. The study coordinator will take minutes for DSMB meetings for board approval.

Meeting Format: Meetings will consist of open and closed sessions.

Open session: Each DSMB meeting will have an open session, including investigators and DSMB members. The open session will generally focus on study conduct (e.g., recruitment and retention; data quality) and allows the DSMB to interact with study leadership and raise issues and discussions about the conduct of the study.

Closed session: Following the open session, the DSMB meets in closed session to allow private discussions and time to deliberate without any study staff present.

Outcomes: Study coordinator will write up a summary of each meeting, noting the date/time and means of communication (e.g., in-person, teleconference, etc.). The DSMB Chair will write up recommendations from the closed session and submit to [SPONSOR] and the PI.

PI will share DSMB outcomes with:

- other investigators involved with the study,
- the IRB (should be provided feedback on a regular basis, including findings from adverse-event reports, and recommendations derived from data and safety monitoring).
- [Sponsor], (must be notified of any actions taken by the IRB)
- if appropriate, applicable regulatory agencies.

Remuneration: DSMB members will each receive a [dollar amount] honorarium per meeting, to be paid by [institution] with funds from the [sponsor, grant number].