HUB Data Safety and Monitoring Board
Charter

Purpose:
This independent Data Safety and Monitoring Board (DSMB) was established to ensure the safety of research participants and the integrity of study data. It will periodically monitor progress, efficacy, safety, and other confidential data from grant projects affiliated with the HUB. Outcome data will be privileged and shared only with members of the DSMB and kept confidential.

Safety Review:
The DSMB review will be centered in analysis of Adverse Events (AEs) and Serious Adverse Events (SAEs) including their occurrence, grading and causality. The Board will consider dropout rates and reasons, hypothesis validation, analysis of outcome data and its relationship to potential modifications in study design, and patient/participant complaints, in their written responses.

We will request the following be included in the Data Safety and Monitoring Plan (DSMP) from PIs:

- Copy of the Consent Form
- General Description
- Anticipated AEs
- Study Stopping Rules
- Reporting Flowchart

General Safety Reporting Expectations:
All safety reports will be sent to the PI of a project. The PI will then report the event to the IRB. A copy of the report will also be sent to the DSMB. If the AE/SAE poses an immediate risk of serious harm to a participant or others, it will be reported to the IRB immediately and the PI will follow their Study Stopping Rules. A summary of all AEs and SAEs will be created by the research team and submitted to the DSMB to review at regularly scheduled meetings. The DSMB will evaluate all AEs/SAEs and include any significant actions that need to be taken and make recommendations regarding the safety of continuation of the study within the meeting minutes. Any IRB/DSMB recommendations from reported AEs/SAEs should be implemented immediately.

Study Stopping Rule:
Traditionally, clinical trials have been required to contain 'stopping rules', which are essentially a set of criteria that specify when dosing an individual subject, cohort and/or trial should be suspended. They are usually based on the occurrence and number of severe and serious AEs. These will be shared with the DSMB within the DSMP.

Membership and Responsibilities:
The Board membership should have at least three or five members in total (always an odd number). A chairperson will be appointed and will be responsible for overseeing the meetings, developing the agenda, and summarizing the meeting. The chairperson is the contact person for the DSMB.

- Trina Radske-Suchan – **Chairperson** (Iowa Community HUB)
- Bery Engebretsen, Chief Visionary (Primary Health Care)
- Liz Fridley, Health Promotion Director (Iowa HHS, Division of Aging and Disability Services)
- Paul Mulhausen, Chief Medical Director (Iowa Total Care)
- Angela Shanahan, RN Clinical Informaticist (MercyOne Des Moines)

The PI and study staff may opt to attend the meetings for informational purposes but must be excused from portions of the meetings which involve voting and final decision-making (see confidentiality section, below). A Board member may recuse themselves from voting on a particular grant project if they feel there is a conflict of interest regarding that project.

Each Board member will make sure to be familiar with the protocol, the DSMP, and the informed consent document of the grant projects. In addition to annual meetings, Board members will be available for ad hoc meetings if necessary. Board members may request from the P.I. any additional data or literature required to comprehensively evaluate safety issues.

Meeting Structure:

Frequency

We will collectively host a DSMB annual online meeting where we will be provided updates on recruitment, enrollment, participant safety reports and status of the ongoing projects. The Board may decide to meet more often if a project presents higher risk to the subjects, the population is vulnerable, or when there is a large volume of data to review. The Chairman may also call an ad hoc meeting depending on safety or efficacy concerns. Meetings will be customarily conducted online.

Content

The content and structure of DSMB meetings will generally include three parts:

1. An open session in which PIs and possibly other study staff involved with clinical trials may be in attendance, at the request of the DSMB, to give a brief update/review of their project, to review the conduct of the trial, to discuss outcome results, and answer questions from members of the DSMB. Issues discussed may include accrual, protocol compliance, and adverse events or safety issues. The PI will provide the Board with any specific information that was determined at the pre-enrollment meeting.
2. A closed session involving the DSMB members only where the Board may discuss the following:
    - determine adherence to treatment plan
    - review interim analysis, if applicable, and determine specific data to be analyzed
    - evaluate end point/stop point rules
    - review protocol violations and deviations to assess adequacy of study
    - ensure documentation of informed consent
    - evaluate reports of adverse events/serious adverse events
    - enrollment
        - followed eligibility criteria

- enrollment numbers
- visit compliance
- screening failure information

- discuss PI or key personnel changes
- review completeness and quality of data collection forms
- review vital signs, clinical tests, etc.
- review confidentiality

3. A final vote by the DSMB members in order to come to a consensus about further recommendations or actions required:
    - continuing the trial unchanged
    - modify the protocols and/or consent form
    - terminate the trial

Record Keeping

Minutes of each meeting will be recorded, kept confidential and securely stored.
Copies of the minutes will be shared with the PI, IRB, and if necessary, appropriate funding and regulatory agencies. The minutes should indicate whether the study should continue as originally designed, whether the study should be modified to protect patient safety or whether the study should be terminated.

Minutes of meetings must be kept confidential until study is completed; stored in a secured, limited access manner.

Recommendations

Recommendations from the DSMB will be given to the PI. The DSMB will provide adequate rationale for all recommendations.

Confidentiality

No communication of DSMB deliberations will be provided to any individual outside of the DSMB membership, except internal and external regulatory reporting. Each member of the DSMB will sign a statement of confidentiality. Protected health information will not be available to the committee.

The study investigators may participate in open session meetings with the permission of the DSMB. The study investigators will not attend closed session meetings.