HRP-335 | 3/29/2024

WORKSHEET: Data and Safety Monitoring

The purpose of this worksheet is to provide support for IRB members reviewing data and safety monitoring plans.

1. Data and Safety Monitoring Plan. Applicable to Minimal risk research and greater than Minimal risk research. (Check if “Yes”. Check all that apply)

The monitoring plan will be conducted by one or more of the following persons or entities:

Principal Investigator

Study team

Sponsor

Medical Monitor

External monitor, independent of the study team

Internal Data Monitoring Committee

NIH sponsored cooperative group

Data and Safety Monitoring Board or Committee (Required for planned emergency research and generally recommended for controlled trials comparing rates of mortality or major morbidity). **Complete Section 3**.

The monitoring plan adequately addresses the following, commensurate with the risks, size, and complexity of the protocol:

Enrollment, avoiding unnecessary exposure to risks

Adverse events

Outcome data

Data completeness

Protocol non-compliance

New and relevant information

Frequency of data review

Frequency of written reports

When appropriate, the monitoring plan for adverse event identification and reporting includes the following:

Grading scales

Attribution scale

Methods used to capture adverse events (e.g. subject interview, lab tests)

To whom adverse events will be reported, and time frame for reporting at a minimum of annually, with unexpected and serious adverse events reported and reviewed immediately, as they occur.

When appropriate, the monitoring plan includes data and safety monitoring criteria for decision-making regarding continuation, modification, or termination of the individual participant or clinical study, including interim statistical analysis/early termination rules (i.e. stopping rules), are included.

For greater than Minimal risk research that will not use a data monitoring committee or board, the plan includes statistical tests or procedures for analyzing the safety data to determine whether harm is occurring.

For studies that involve potential identification of suicidality in research participants or participants at who are at an elevated risk of suicide, the IRB’s Guidance on Suicidality in Human Research must be considered (see Appendix B-7 in the Investigator Manual (HRP-103)). The PI’s data and safety monitoring plan should include the following:

Consent/Assent form(s) have language about the inclusion of sensitive questions and potential confidentiality limitations.

Qualifications and training for study team members designated to carry out data & safety monitoring plan is appropriate.

Appropriate plan for monitoring participants’ responses and, when appropriate, follow-up to minimize risks:

For online surveys that collect identifiable information, the study includes a plan for assessing the level and immediacy of risk (e.g., timely review of survey responses, who will conduct the assessment, means of communication, timeline for contact, types of questions, specific score/response cut-off points. The study team should also provide [a list of referral resources](https://research.umn.edu/units/irb/toolkit-library/templates-forms) with the consent form.

For in-person activities, the protocol and consent form include a statement that measures of suicidality scores will be evaluated prior to the participant’s departure from the research visit. In addition, if there is a concern about the participant’s safety, a qualified member of the research team will remain with the participant until support services have been received for example.

Longitudinal research or clinical trials include procedures for withdrawal or termination due to clinical worsening or suicidality.

When appropriate, end of study procedures include linkage to care or continuation of follow up assessments.

1. Monitoring the Quality of Data

The DSMB Charter or the protocol adequately addresses one or more of the following:

Internal data monitoring, such as a weekly review of case report forms for accurate completion.

Statistical monitoring, such as use of software or statistical services.

Planned audits for data integrity and compliance, such as the use of a monitoring service.

1. Data and Safety Monitoring Board (DSMB)[[1]](#endnote-2)

DSMB Charter Composition includes the following:

Purpose

Roles and Responsibilities

Operation and Format

Monitoring Guidelines

Reporting processes to and from the DSMB

Research data to be monitored and how data will be provided

DSMB Membership includes the following (check all that apply):

Includes at least 3-5 members with appropriate expertise.

For protocols that involve efficacy assessment, membership includes a biostatistician.

For protocols that involve unusually high risks or with broad public health implications, consider the involvement of a medical ethicist.

Members are independent from the direct management of the research study.

Members do not have a conflict of interest or other conflicting commitment (e.g. co-Investigator or direct report of any PI or Co-Investigator).

DSMB meetings are held at a frequency that is commensurate with the risks, size, and complexity of the protocol (check one):

DSMB will meet at least annually

DSMB will meet quarterly or semi-annually if protocol involves high risk, vulnerable populations, or a large volume of data.

DSMB will meet more frequently, specify: *Click or tap here to enter text.*

1. The DSMB is required for planned emergency research and generally recommended for controlled trials comparing rates of mortality or major morbidity. [↑](#endnote-ref-2)