Ascension Wisconsin Research Integrity and Protection

Data and Safety Monitoring Plan Guidelines

For research that involves greater than minimal risk interventions, the IRB requires the investigator and/or the industry sponsor to have a Data and Safety Monitoring Plan (DSMP) in place that protects the safety of participants, the validity of the data, and the integrity of the research study. The IRB reviews the plan and determines if the plan has adequate provisions in place for monitoring the data collected to ensure the safety of participants.

This document provides investigators and research teams with guidance on how to develop a Data and Safety Monitoring Plan (DSMP).

What is a Data and Safety Monitoring Plan?

Data and safety monitoring provides a clinical investigation with a system for appropriate oversight and attention to the protection of human participants by the investigator, research team, or an independent reviewer. A DSMP is a quality assurance plan for a research study. A written DSMP prospectively identifies and documents monitoring activities intended to protect the safety of the participants, the validity of the data and the integrity of the research study. The DSMP may also identify when to terminate a subject's participation (i.e. individual stopping rules) and/or the appropriate termination of a study (i.e. study stopping rules). The DSMP may or may not include a Data Safety Monitoring Board (DSMB).

When should a Data and Safety Monitoring Plan be submitted?

The criteria for approval of research states that when the research involves more than minimal risk, the research plan makes adequate provision to monitor the data collected to ensure the safety of participants, and that adequate provisions to protect the privacy of participants and the confidentiality of the data are maintained (45 CFR 46.111).

The IRB expects all studies that involve administration of an investigational agent or use of an investigational device or use of an approved agent or device that has the potential for mortality or major morbidity will have a written DSMP or an established DSMC. A DSMC may also be required for studies that have a high expected rate of morbidity or mortality in the study population.

If the research is considered minimal risk, then the development of a DSMP may be helpful, but its development is not required by the IRB unless, the IRB determines a DSMP is needed for the oversight of the study.

How Do I Submit a DSMP?

The data and safety monitoring plan can be incorporated within the protocol, documented within the IRB application or in a separate document. If there is an independently established DSMB, there is often a DSMB charter. If the protocol references a charter, a charter should be provided. If the study has an external Sponsor, the Sponsor typically provides the DSMP description, although the investigator may need to provide some supplemental details of the local plan.

Recommended Elements of a Data Safety Monitoring Plan

A DSMP should include a general description of a plan establishing the overall framework for the oversight and monitoring of a study. The minimum required DSMP content should include the following elements:

1. Summary of the Protocol:
    - A brief description of the study design (i.e. interventions, procedures, tests and scans, biospecimen collection, interviews and focus groups, study visits, etc.)
    - Primary and secondary outcome measures/endpoints, sample size and target population.
2. Trial Participant Safety:
    - Description of the potential risks and the measure in place to protect participants against foreseeable risks.
    - Description of any specific events that would preclude a participant from continuing the intervention.
    - Description of any procedures in place for managing any medication related issues (i.e. washout, allergic reactions, drug interaction, discontinuation of medication, use of rescue medications).
3. Data and Safety Monitoring
    - Identification and description of individuals responsible for monitoring the trial, their roles, qualifications, and the frequency of the monitoring activities. If the monitoring entity is a DSMB, provide a DSMB charter if available.
    - How the study will monitor site performance.
4. Data Management and Analysis:
    - Data collection, entry and transmission methods.
    - Description of the data security in place to protect the confidentiality of the data.
    - Description of the quality assurance procedures in place to ensure the integrity of the data.
    - Data analysis plan, including a description of the trial stopping rules for the study.
5. Reportable Events:
    - Description of the process and timelines for collecting and reporting Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) to the appropriate monitoring and regulatory entities.

References

- FDA Guidance for Clinical Trial Sponsors; Establishment and Operation of Clinical Trial Data Monitoring Committees
- FDA Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs: Improving Human Subject Protection
- NIH Policy for Data and Safety Monitoring and other NIH policy and guidance on DSMP