IRB SOP 1204
Data Safety Monitoring Plan

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe Institutional Review Board review of data and safety monitoring plans (DSMP) to ensure adequate protection is in place for study participants.

Scope

This SOP applies to all clinical research in which the USA Institutional Review Board is the IRB of record.

Applicability

This policy applies to all research studies (i) involving greater than minimal risk, or NIH funded/FDA regulated clinical trials and (ii) all investigator-initiated clinical research studies, regardless of risk.

Definitions

Data Safety Monitoring Plan (DSMP): A DSMP describes how the Lead Researcher plans to oversee the research participant's safety and welfare, and how adverse events will be characterized and reported.

Data Safety Monitoring Board (DSMB): A DSMB (or DMC) is a formally appointed group that will conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study and integrity of the accumulating data.

Policy

It is the responsibility of the IRB to ensure the study site has appropriate measures to monitor the data in order to maintain the safety of the patients and the integrity of the study data. The IRB should review all studies for the presence and adequacy of the PI's monitoring plan.

1.0 Data Safety Monitoring Plan

A Data Safety Monitoring Plan (DSMP) is a written procedure that describes how the Principal Investigator plans to oversee the human subject's safety and welfare throughout the course of the study. The level of detail in the plan should be based upon the degree of risk to the subjects. The intensity and frequency of monitoring should be tailored to fit the expected risk level, complexity, and size of the particular study. Review of safety reports and trial data by a Data Safety Monitoring Board (DSMB) or medical monitor may be part of a DSMP, but it is not the entire DSMP. A DSMP is required for all research that is not exempt under Federal Regulations applicable to Human Subjects Research.

A Data and Safety Monitoring Plan (DSMP) is unique to a particular study. Appropriate DSMPs may fall anywhere along a continuum from monitoring by the principal investigator or group of investigators to the establishment of an independent Data and Safety Monitoring Board (DSMB). Safety monitoring may be accomplished as follows:

- The investigator performs the safety monitoring. (This would be appropriate for a singlesite open label trial.)
- An uninvolved expert in the research topic performs the safety monitoring. (This would be appropriate for a single site blinded trial.)
- The sponsor's medical monitor performs safety monitoring.
- The sponsor's safety monitoring committee performs safety monitoring.
- An independent data and safety monitoring board (DSMB) performs safety monitoring. Regardless of the type of DSMP, the individuals participating in the monitoring plan must be objective.

2.0 Data Safety Monitoring Board

A Data and Safety Monitoring Board (DSMB) is an independent group of experts that advises the sponsor and the study investigators. The members of the DSMB serve in an individual capacity and provide their expertise and recommendations. The DSMB evaluates research data on an ongoing basis to assure participant safety and study integrity. The DSMB periodically reviews study data and unanticipated problems and makes recommendations based on their reviews along with assessing the performance

of overall study operations and any other relevant issues, as necessary. The following is a list criterion for the use of a DSMB:

- Multi-site clinical trials with interventions that entail risk(s) to participants
- If the trial is evaluating mortality or another major endpoint, such that

2.0 Investigator Responsibilities

Investigators will submit the DSMP in writing as part of the initial IRB submission. The elements that encompass a DSMP may be incorporated in the protocol. If placed in the protocol, a separate DSMP is not needed as long as the protocol adequately addresses the essential elements of a DSMP.

Depending on the extent and severity of expected harms in a research study, the DSMP should include provisions to determine whether the character, incidences, and severity of harms match expected harms and should describe the stages of research at which monitoring will occur (e.g., specific points in time, after a specific number of subjects have been recruited, upon recognition of harms). Monitoring may be conducted by investigators themselves, a medical monitor, a data safety monitoring committee, or other appropriate mechanism for the research activity. The Investigator should also include the process to unblinding and the criteria, if any, to stop administration of the product due to safety concerns.

2.1 Central Data Safety Monitoring Board

The Investigator should indicate on the initial IRB application that a central DSMB will be utilized.

At the time of continuing review, the Investigator should submit the most recent DSMB recommendation. This recommendation should not be older than one year from the continuing review date.

Any recommendation made by the DSMB that references concerns for subject safety or data integrity should be submitted to the IRB within 5 business days of receipt.

2.2 USA Data Safety Monitoring Board

The Investigator should indicate on the initial IRB application that the USA DSMB will be utilized.

At the time of continuing review, the Investigator should submit the most recent DSMB recommendation. This recommendation should not be older than one year from the continuing review date.

Any recommendation made by the DSMB that references concerns for subject safety or data integrity should be submitted to the IRB within five (5) business days of receipt.

Regulated Documents

45 CFR 46.101(b)
45 CFR Part 46, Subpart C 46.301-306

University Related Documents