UNIVERSITY OF SOUTH ALABAMA

Policy No:
Responsible Office: Office of Research Compliance and Assurance
Last Review Date: June 2021
Next Required Review: June 2026

Data and Safety Monitoring Board

1. Purpose

An independent Data and Safety Monitoring Board (DSMB) will be convened to assess the progress of a clinical study, the safety data, and critical efficacy endpoints (if appropriate) and provide recommendations to the PI. The members of the DSMB serve in an individual capacity and provide their expertise and recommendations. The DSMB will review cumulative study data from all participating sites to evaluate safety, study conduct, and scientific validity and data integrity of the study.

2. Applicability

Not all studies require the use of a DSMB. All studies should be evaluated by ORCA and the IRB to determine the need for a DSMB based on the study design, risk to patients, funding agency, and other concerns. A study with any of the following criteria should utilize a DSMB:

- Multi-site clinical trials with interventions that entail greater than minimal risk(s) to participants
- If the trial is evaluating mortality or another major endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications.
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Data Safety and Monitoring Plan (DSMP): a specific plan, developed by the local principal investigator (PI), that outlines how study progress will be monitored throughout the course of the research to ensure the safety of subjects as well as the integrity and confidentiality of data.

Institutional Review Board (IRB): an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

Office of Research Compliance and Assurance (ORCA): an office that works with research oversight committees, boards and offices responsible for specific components of research compliance to ensure compliance with all regulatory requirements related to research activity. The office is responsible for monitoring regulatory changes and recommending institutional responses to ensure compliance, and the oversees development and implementation of policies, procedures, programs and educational activities which satisfy federal, state and institutional regulations governing the conduct of research.

Quorum:

- To review all documents submitted to the DSMB for review
- To review the conduct of the study, including protocol violations
- To review data on participant recruitment, accrual, and retention, as well as assessments of data quality, completeness, and timeliness
- Protect the confidentiality of the study data and the DSMB discussions
- To make recommendations to continue, modify, or terminate the study

4.3.3 DSMB Chair Responsibi (t)lnr-3 (n)2.MC /LBody <.3 (i)10.6n Th (n)2. following r (n)2.MC /4 (p)13

- Disseminate documents to DSMB prior to the scheduled meeting
- Maintain confidentiality of documents submitted for DSMB review, Open Session minutes, and DSMB correspondence
- Distributes Open Session minutes to DSMB members
- Facilitates the meetings, assists in the development of the agenda, and ensures that the meeting minutes and recommendation(s) are appropriately documented

4.6 Meeting of the DSMB

4.6.1 Charter Meeting

The first meeting of the DSMB for each new protocol will be a Charter Meeting. This meeting will formally establish the DSMB and begin to acquaint the DSMB members with the protocol or types of protocols that this DSMB will be charged with monitoring. It affords the DSMB an opportunity to recommend final revisions to the Data Safety Monitoring Plan, Protocol, statistical analysis, etc.

The PI must be present of the Open Session of Charter Meeting.

DSMB approval must be received prior to any study related activities.

At the beginning of the DSMB meeting, the Chair will initiate the charter session of the meeting, which will include calling the meeting to order and assuring a duly constituted Board.

Meeting objectives will include:

- The introduction of the DSMB members and an establishment of qualifications for quorum.
- A review of the protocol and DSMP to offer feedback as necessary
- Establishment of meeting frequency based on the risk profile, recruitment rate, protocol design, etc.
- Confirmation and recording of any conflict of interest, if applicable.

As needed, the Charter may be revised after the interim meeting, with the Chair providing sign-off. Changes to the Charter will be clearly delineated in a document, and this document will be associated with the new version.

4.9 Completion of DSMB Activities

The DSMB will remain active until written notification is received from ORCA office that the study has completed.

5.2 Interim Review by the DSMB

5.2.1 Submission of Materials for Interim Meetings

Submit the following materials to Office of Research Compliance and Assurance: Protocol

- x Informed Consent
- x DSMB Report for Open Session
- x DSMB Report for Closed Session if applicable

5.2.2 The ORCA will work with the DSMB members to schedule a convenient date and time to hold the interim meeting.

5.2.3 After the DSMB meeting, an ORCA representative will draft the minutes and a letter to the PI. The DSMB Chair is required to review the minutes and the letter to PI.

5.2.4 The letter to the PI will be sent to the PI and any applicable parties.

5.2.5 The PI is responsible for submitting a copy of the letter to the IRB of record per the IRB's reporting requirements.

5.3 Closure by the DSMB

5.3.1 The Investigator will notify the Office of Research Compliance that the study is closing

5.2.2 The ORCA will work with the DSMB members to schedule a convenient date and time to hold a closeout meeting.

5.2.3 The Investigator will submit a summary of all data regardless of if the study completed or ended prematurely.

5.2.4 After the convened DSMB meeting, the ORCA will send the Investigator an administrative letter demonstrating that t

7.1 Related Regulations and/or Policies

- FDA Guidance: Establishment and Operation of Clinical Trial Data Monitoring Committees.
- 21 CFR 50.24(a)(7)(iv)

7.2 Other Related Documents and/or Procedures

- DSMB Report Form – Multisite – Open Session
- DSMB Report Form – Multisite – Closed Session
- DSMB Report Form – Single Site – Open Session
- DSMB Report Form – Single Site – Closed Session