

Data and Safety Monitoring Board (DSMB) Charter Outline

The DSMB acts as an advisory capacity to the Principal Investigator (PI) and functions in accordance to:

- The requirements of the study
- The risk of the study
- The requests from the PI, Funding Agency, and Sponsor

DSMB will enhance existing institutional infrastructures to ensure:

- Participant safety and ethical human subject research
- Perform technical and feasibility review services for all partner institutions
- Assist members with data safety monitoring plans and data safety monitoring board preparation

Outline of DSMB Charter

1. Title Page

- a. Version, version date, study title, PI
- b. Page footers should include: DSMB charter version and date, study title or abbreviation, and page number (e.g., x of y pages)
- c. A table of contents

2. Introduction

- a. Purpose of DSMB
- b. Optional protocol summary

3. DSMB Responsibilities

- a. Safety Monitoring
- b. Monitor performance of the trial
- c. Stopping rules for safety, efficacy, and/or futility (if applicable)

4. Principal Investigator Responsibilities

5. Sponsor Responsibilities – if applicable

6. DSMB Membership and Role-specific Responsibilities

7. Structure and Conduct of DSMB meetings

- a. DSMB meetings
- b. Quorum and voting
- c. DSMB recommendations
- d. Ad hoc meetings

8. DSMB Operations

- a. Disbanding the DSMB and destruction of documents
- b. Procedures for replacing a member

9. Reports

- a. Minutes
- b. DSMB Recommendations
- c. Reports to PI for IRB review

10. Signature Page

11. Appendices

- a. DSMB membership, affiliations and contact information
- b. Template for recommendations from the closed (executive) DSMB session
- c. Stopping rules