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