STANDARD OPERATING PROCEDURE (SOP)

Data Safety Monitoring Plans (DSMPs) and Data Safety Monitoring Boards (DSMBs)

SOP Number: CR-DSMB-001

Version: 1.0

Effective Date: May 12, 2026

1. Purpose

This institutional SOP establishes requirements for Data Safety Monitoring Plans (DSMPs) and Data Safety Monitoring Boards (DSMBs) for human subjects research. This SOP incorporates requirements for participant safety monitoring, protocol compliance, adverse event oversight, multi-site investigations, DSMB governance, and IRB reporting.

2. Scope

Applies to all non-exempt human subjects research and all investigators, study teams, sponsors, DSMB members, monitors, and IRB personnel.

3. Policy

All non-exempt studies require a DSMP proportionate to risk, complexity, and study size. DSMBs shall be implemented when warranted by study risk, multi-site involvement, mortality/morbidity endpoints, or ethical need for early stopping.

4. Definitions

Include DSMP, DSMB/DMC/DSMC, UP, AE, CAPA, Sponsor-Investigator, CRO, and protocol deviation definitions.

5. Roles and Responsibilities

PI responsibilities, sponsor responsibilities, DSMB responsibilities, monitor responsibilities, and IRB oversight.

6. DSMP Requirements

Monitoring of progress and safety, participant risk assessment, stopping rules, monitoring in multi-site trials, conflicts of interest, reporting of UPs, suspensions/terminations, data accuracy and protocol compliance.

7. DSMP Monitoring Expectations

Frequency of reviews, site monitor identity, monitoring scope, record review percentages, follow-up documentation, confidentiality, and data accuracy expectations for minimal-risk studies.

8. Multi-Site Investigations

Requirements for sponsor-investigator trials and coordinating investigator trials, including centralized monitoring, site visits, self-monitoring, safety communications, FDA reporting, and IRB reporting.

9. DSMB Governance

Purpose, independence, membership qualifications, expertise requirements, conflict disclosures, recusal procedures, gender/ethnic representation, quorum, voting, ad hoc meetings, and documentation.

10. DSMB Responsibilities

Safety review, protocol review, study progress review, AE/UP oversight, stopping rules, published findings review, consultation with investigators, and written recommendations to IRB.

11. Conflict of Interest

COI disclosure and recusal requirements consistent with institutional policy.

12. IRB Oversight

Initial and continuing review of DSMPs, DSMB reports, monitoring results, internal AEs, and protocol compliance.

13. Documentation and Record Retention

Meeting minutes, reports, recommendations, CAPAs, and monitoring logs retained per institutional policy.

14. References

45 CFR 46.111(a)(6), FDA 2006 DMC Guidance, Emory IRB Policies and Procedures, NIH/NIAMS guidance.

Appendix A: DSMB Charter Template Requirements

Include title page, protocol summary, responsibilities, membership, meetings, voting, reports, recommendations, signatures, and stopping rules.

Appendix B: Things to Consider in DSMP Development

Membership, conflict of interest, meeting cadence, quorum, CAPA procedures, monitoring frequency, and reporting expectations.