

**Investigator Responsibilities for Data
Safety Monitoring Plan
Requirements (Greater than Minimal
Risk)**

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POLICY:

- I. For all greater than minimal risk studies, PIs are required to design studies to include a plan for monitoring data to ensure participant safety and data integrity.
- II. NIH Policy requires a Data Safety Monitoring Plan (DSMP) for every grant application or contract proposal submitted to NIH that involves clinical research including physiologic, toxicity, and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). The level of monitoring should be commensurate with scope and risk of the research.
- III. The DSMP should provide a general description of the overall framework for data and safety monitoring. It should address the following areas, as applicable:
 - A. What will be monitored;
 - B. How often data and safety will be monitored;
 - C. Who will monitor;
 - D. Where monitoring will occur;
 - E. How the clinical study sites, research pharmacy(ies), and core laboratory(ies) will be monitored; and/or
 - F. How adverse events will be assessed and reported.
- IV. In accord with NIH policy, the DSMP for Phase III clinical trials must include an independent data and safety monitoring board

PROCEDURE:

- I. The PI must submit materials regarding data monitoring to the IRB and provide sufficient detail so that the IRB is able to make determinations required by the federal regulations for research approval.
- II. The IRB evaluates the research plan to determine that it contains adequate provisions for monitoring the data collected to ensure the safety of participants by reviewing the submitted materials in the IRB application.

REFERENCES:

[38 CFR 16.111\(a\)\(6\)](#)

[45 CFR 46.111\(a\)\(6\)](#)

[21 CFR 56.111\(a\)\(6\)](#)

[VHA Handbook 1200.05, Section 10](#)

[*NIH POLICY for Data and Safety Monitoring \(June, 1998\)*](#)

[*NIH Guide: Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials \(June 2000\)*](#)