



I. Policy

A. Introduction

Investigators develop data and safety monitoring plans as a mechanism for assuring the safety of human subjects and human research data, the validity of data, and the appropriate termination of studies. The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or clinical investigations funded by the National Institutes of Health (NIH) or regulated by the Food and Drug Administration (FDA).

B. Scope

This policy specifies requirements for appropriate use and establishment of a data and safety monitoring plan for clinical research protocols to ensure the safety of subjects, the accuracy of data, and the appropriate termination of the study.

C. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the [MUSC IRB Resources & Guidance Webpage](http://research.musc.edu/ori/irb/resources.html) (<http://research.musc.edu/ori/irb/resources.html>)

II. Definitions

The definitions for the following terms used in this document may be found in the HRPP Program Guide Section 1.3 - Definitions of terms:

- A. Data and Safety Monitoring Plan**
- B. Data and Safety monitoring Board**

III. Guidance on Data and Safety Monitoring Plans (DSMPs)

- A.** A Data and Safety Monitoring Plan is intended to assure the safety of the human subjects, and the validity of the data generated. The essential elements of the plan include:
 - 1. What data is to be monitored
 - 2. Who is responsible for monitoring and how often
 - 3. Reporting plan for communicating findings to IRB/Sponsor/Federal Agencies
 - 4. Reporting plan for adverse events
 - 5. Endpoints Proposed
- B.** A Data and Safety Monitoring Plan must appropriately consider several criteria including the potential risks, nature, size, and complexity of the research protocol, as well as the subject population. A DSMP is commensurate with the risks involved with the investigation and can involve the principal investigator submitting an annual safety and adverse event report to the IRB, or establishing a formal Data and Safety Monitoring Board (DSMB).
- C.** All multi-site clinical trials, all investigator-initiated Investigational New Drug trials, and all investigator-initiated Investigational Device trials involving interventions that entail potential risk to the participants must have a DSMB included in the Data and Safety Monitoring Plan. The IRB will review and approve the adequacy of Data and Safety Monitoring Plans.
- D.** A DSMB is a formal committee that is established specifically to monitor data throughout the life of a study to determine if it is appropriate, from both the scientific and ethical standpoint, to continue the study as planned. A DSMB may consist of as few as 3 members, but this number should be large enough to include a representation of all needs/skills and experience. The membership of the DSMB cannot have any actual or perceived conflict of interest associated with the study.

IV. Procedures

- A. The principal investigator will submit a detailed Data Safety and Monitoring Plan as part of the protocol submission to the IRB. If the Data Safety Monitoring Plan includes a DSMB, the following should be considered regarding DSMB composition: relevant expertise, experience in research, experience as a member of other DSMBs, and a lack of conflict.
- B. The IRB will review the plan in conjunction with the protocol review to determine the adequacy of the plan to minimize risks to subjects and to support data integrity including the adequacy of interim reporting to the IRB.
- C. Any modifications in the plan required by the IRB will be communicated in writing to the principal investigator.
- D. The principal investigator is responsible for submitting the DSMB reports at the time the reports are available to the Investigator, regardless of the timing of the report in relation to the continuing review of the study. These reports should follow the timeframe as specified in the IRB approved protocol.

V. References

- A. [NIH Policy for Data and Safety Monitoring](#)
- B. [Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials](#)