Policy Name: **Data and Safety Monitoring Plans**			
Approved			**Date: 11/01/08**
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I. POLICY

A. Introduction

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.

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.

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. Interventional Clinical Risk
B. Minimal Risk

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.

C. 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.

D. 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 membership of the DSMB cannot have any actual or perceived conflict of interest. The IRB will review and approve the adequacy of Data and Safety Monitoring Plans

IV. PROCEDURES

A. The principal investigator will submit a detailed Data Safety and Monitoring Plan as part of the protocol submission to the IRB.

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.

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