Subject: Procedure for Data and Safety Monitoring Plans

Procedure:
This procedure outlines the use of data and safety plans to assure extra protections and safety in research involving humans.

I. Investigator Responsibilities.
   A. It is the responsibility of the Investigator to identify the Data Safety Monitor (DSM) or the Data Safety Monitoring Board (DSMB) in the initial IRB “Application for Human Research”.
   B. The Investigator will provide a detailed description of the data safety monitoring plan (DSMP) in the initial application as well as the study protocol. This is required even in the absence of a DSM or DSMB.
   C. All DSM or DSMB reports are to be submitted to the IRB within 10 days of receipt by the Investigator when the report identifies a new risk or a change in the risk-potential benefit profile. An amendment will accompany the reports along with the amended documents (e.g., consent document, IRB application).

II. IRB Committee Responsibilities.
   A. The IRB Committee, IRB Chair or designated Committee Member will review the initial IRB “Application for Human Research” to assure the adequacy of the Data Safety Monitoring Plan (DSMP) in relationship to the size, complexity, and level of risk of the proposed research.
   B. The IRB Committee, IRB Chair or designated Committee Member will review the qualifications and experience of the DSM or the composition of the DSMB including the qualifications and experience of the individual members. The IRB may make recommendations regarding expertise, frequency of meetings, etc., to the Investigator for the enhancement of human participant protections.
   C. The IRB Committee, IRB Chair or designated Committee Member may request additional information or clarification regarding the DSMP, DSM, or DSMB.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will conduct a pre-review of the IRB application and verify the inclusion of a data and safety monitoring plan regardless of the level of review requested (excluding “exempt” research).
   B. The RCA will correspond with the Investigator or the study contact if the protocol submitted lacks adequate plans for assuring proper data collection and participant safety.
   C. The RCA will assist the Investigator or study contact in meeting the IRB requirements for a DSMP.