Guidelines for a Data and Safety Monitoring Plan for IRB Review

In order to approve research in which the IRB considers whether the provisions for monitoring data to ensure the safety of research participants are appropriate, the IRB must determine that the research plan makes adequate provisions for monitoring the data. Address all of the following items when submitting a Data Safety Monitoring Plan for Institutional Review Board (IRB) review.

- Include the principal investigator(s) (PI) name, IRB protocol number, and title of the study.

- Describe the type of data or events that are to be monitored during the study.

- Explain the frequency of assessments of data or events captured by the monitoring provisions (e.g., at certain points in time or after enrollment of a certain number of subjects).

- Identify the entity or person(s) responsible for monitoring the data collected, including data related to unanticipated problems and their respective roles in the research activities (i.e., PIs, research coordinators, statisticians, independent medical monitor, etc.). Note: -For studies that do not have or are not required to have a data monitoring committee (DMC) and are blinded, have multiple sites, enroll vulnerable populations or employ high-risk interventions, the IRB will carefully review the DSMP and determine whether a DMC is needed.

- If not using a DMC, describe procedures for monitoring study progress including specifics of how monitoring the data and assuring safety of subjects will occur (e.g., statistical or other evaluations to assure that participants are not being harmed).

- Explain procedures for minimizing research-related risk.

- Identify procedures for analysis and interpretation of the data.

- Describe the procedures and time frames for reporting unanticipated problems to the IRB (and other entities, if applicable).

- Explain the definition/s of specific triggers or stopping rules that will dictate when some action is required and then describe what the range of possible actions will be.

- Describe how data accuracy and protocol compliance will be assured.

- Describe the composition of the Data Safety Monitoring Board (DSMB), if applicable.