**Data and Safety Monitoring Plan**

**Principal Investigator**:       **Protocol Number**:

1. Describe the type of data or events that will be monitored during the study.

1. Describe the frequency of assessment of data or events that will be monitored (e.g., certain points in time after enrollment or after a certain number of participants are enrolled).

1. Who will be responsible for monitoring the data/events?
2. Describe how monitoring of data and assuring safety of participants will occur (e.g., statistical or other evaluations to assure that participants are not being harmed)?

1. What procedures will be used for analysis and interpretation of the data?

1. Describe the procedures and timing of reporting unanticipated problems to the IRB (and other entities, if applicable).

1. Describe the specific triggers or stopping rules that will dictate when actions are required and the range of possible actions that may be taken.

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

1. If there will be a Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) established, describe the composition (Members of the committee/board and their expertise).

[ ]  N/A