Sample Data Safety and Monitoring Plan

1. **Face Page**: Identify personnel and contact information

2. **Brief Description of Study**: May use protocol abstract

3. **Risk Assessment**: Estimate risk level

4. **Plan for Monitoring and Safety Review**:
   a. Specify the name and contact information of the individual responsible for monitoring the safety environment of the participants (i.e. PI only, or additional monitoring by a Medical Monitor, Safety Officer, Independent Committee, or DSMB).
   b. Specify what will be monitored (i.e. subject eligibility, adherence to treatment plan, documentation of dropouts, evaluation of primary and secondary endpoints, adverse events, and/or problems with informed consent).
   c. If a DSMB is required, describe the composition of the board, what role the board will play, and the frequency of meetings. Confirm that the PI, IRB, and other appropriate entities will receive all reports of DSMB meetings and other aggregate data analyses that may be indicated in evaluating subject safety.

5. **Plan for Data Management**:
   a. Indicate who is responsible for collection and storage of data, where it will be stored. (i.e. lab notebook, database) and any security measures needed to protect data from inadvertent loss or inappropriate use.
   b. Include a description of how often interim data will be reviewed and by whom.
   c. Specify any conditions that would necessitate early termination of the study (i.e. some clinical trials require documentation of stopping rules that might be used if the participants are found to be exposed to excessive risks in relation to anticipated benefits).
   d. Indicate who will perform aggregate analysis of data and adverse events, if applicable.

6. **Plan for Adverse Event Reporting**:
   a. Indicate the name and contact information of the individual(s) responsible for monitoring and reporting the occurrence of adverse events throughout the study, whether they are anticipated, unanticipated, or serious, and the frequency of monitoring (annual, 6 months, other).
   b. Describe the anticipated adverse events listed in the Consent Form for this protocol. State your plan for how these will be reported and to whom (i.e. IRB, FDA, NIH).
   c. Identify the scale that will be used to grade the severity attribution of adverse events. You may be guided by The Common Toxicity Criteria (CTC) scale available at: [http://ctep.cancer.gov/](http://ctep.cancer.gov/), or another scale of your choice.
   d. Indicate that you will follow Section 9-1 "Unanticipated Problems" in the HRP Manual on mandatory reporting of Serious Adverse Events (SAEs), and report them to the appropriate people within 24 hours of occurrence or recognition.

7. **Human Subject Training**:
   Specify that all key research personnel have completed the MSU required Human Subjects Training.