

Sample Data and Safety Monitoring Plan

NIH Study Number:

Title:

Principal Investigator:

I. Overview

- A. Brief description of the purpose of the study.
- B. Adherence statement. The Data and Safety Monitoring Plan (DSMP) outlined below for (*insert grant #*) will adhere to the protocol approved by the *Institution* IRB (*and any other committees that have approved the protocol*).

II. Adverse Events

A. Adverse event assessment

1. 1. The DSMP should outline expected risks:
 - Outline the risks that are expected as part of participation in the study
 - Delineate any specific events that will be tracked, based on the protocol
 - Provide a statement that these risks are addressed in the protocol and consent form
 - Delineate steps that will be taken to minimize these risks
2. State how each subject will be evaluated for adverse events
3. *The following information is provided for assistance in the development of this section of the DSMP. More detailed information about adverse events can be found on the OHRP website (<http://www.hhs.gov/ohrp/policy/advevntguid.html>). The assessment/reporting of adverse events will vary with the nature of the study and/or any applicable regulatory requirements.*

An adverse event (AE) is any untoward medical occurrence in a subject temporally associated with participation in the clinical study or with use of the experimental agent being studied. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.) or any combination of these.

An adverse event can be an expected side effect that is of a serious nature, or an unexpected side effect/event regardless of severity.

All events should be graded as to their attribution (related or unrelated) and their severity. Generally, the DSMP should include a statement about whether unblinding will be used as a measure to assess attribution. If unblinding is used, provide steps to be taken to minimize the risk of bias.

OHRP defines a Serious Adverse Event (SAE) as any adverse event that meets one of these criteria:

- The event results in death*
- The event is life-threatening*
- The event results in an inpatient hospitalization or prolongation of existing hospitalization*
- The event results in permanent or severe disability or permanent damage*
- A pregnancy results in a congenital anomaly or birth defect*
- Based on appropriate medical judgment, the event may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above*

B. Adverse event reporting

1. State that every event that is reported to either the principal investigator or the designated research associates by the subject or medical staff caring for the subject and which meets the criteria will be documented
2. State that an adverse event report will be generated for each event and what will be included in the report (e.g., description of the event, when and how it was reported, as well as any official chart records or documentation to corroborate the event; determination of attribution)
3. List all recipients of the report (examples include safety officer, DSMB, IRB, GCRC, commercial sponsor, NIDDK program official)
4. State the timeline for reporting adverse events. If the study is conducted under an IND/IDE, discuss FDA reporting regulations. The timeline should distinguish between anticipated /unanticipated and related/unrelated events.
5. State that any action resulting in a temporary or permanent suspension of this study (e.g., FDA actions, IRB actions, or actions by a commercial sponsor or by the investigators or co-investigators) will be immediately reported to the appropriate NIDDK program official.

III. Safety Review Plan and Monitoring

Oversight of participant safety includes review of adverse events as well as study progress, data integrity and study outcomes.

- A. Justification of sample size
- B. Safety and study progress reviews
 1. State who will review the adverse events (e.g., principal investigator, safety officer, DSMB, etc.) and how often. The qualifications of the safety officer and/or DSMB members must be provided to NIDDK for approval.
 2. State who will review study progress (e.g., recruitment, retention, protocol adherence) and how often.
 3. Delineate what will be provided in the annual report, including, for example: 1) list and summary of adverse events; 2) whether adverse event rates are consistent with pre-study assumptions; 3) summary of recruitment and retention and reason for dropouts; 4) whether the study is on track to be completed and accomplish the stated aims.
- C. Stopping Rules (if any)

IV. Informed Consent

Informed consent will be obtained from each subject at entry into the study. Describe the informed consent process.

V. Data Quality and Management

- A. Describe measures (including a timeline) to be taken to review data collection forms for completeness and accuracy of the data as well as protocol compliance.
- B. Describe measures taken to insure data integrity and protection of databases.

VI. Confidentiality

Describe measures taken to protect subject privacy.