

Monitoring Plan

Appendix A: **Template Monitoring Plan**

UPCC DATA SAFETY AND MONITORING PLAN

Title of Protocol
Principal Investigator
Protocol Number

PURPOSE:

The Data Safety Monitoring Plan is written to ensure the safety of the participants and verifying the validity and integrity of the data.

RISK OF STUDY:

- Low
- Moderate
- High

Justify level of risk: _____

IND HOLDER:

- NCI
- Industry Sponsor
- PI
- Exempt
- Other, specify _____

WHO WILL BE RESPONSIBLE FOR MONITORING? (check all that apply)

- Principal Investigator and research coordinator
Names: _____
- This study will be monitored by an external group (i.e., pharmaceutical sponsor, contract research organization, CRO).
 - I have confirmed that the industry sponsor oversees the data and safety monitoring relevant to the conduct of this protocol.
 - This is a NIH Sponsored Cooperative Group protocol so there is DSMP in place.
- Medical Monitor
- Safety Monitoring Committee
- Data Safety Monitoring Board (DSMB)

HOW WILL MONITORING BE PERFORMED?

During the course of the study, safety and data quality monitoring will be performed on an ongoing basis by the Research Coordinator and the Principal Investigator. The clinical research coordinator (if there is one, or the PI) is responsible for collecting and recording all clinical data. This includes ensuring that all source documents exist for the data on the case report forms, ensuring all fields are completed appropriately, and all corrections are done according to Good Clinical Practice (GCP's). Any inconsistencies/deviations are documented. The P.I. will review lab results for each patient on an ongoing basis and will document his/her review by initialing and

dating each lab and or x-ray report. In addition, this study will be audited by CTSRMC in accordance with the UPCC Policy and Procedure for Auditing Clinical Protocols.

Monitoring Plan

(For studies that require a medical monitor, an independent monitor, a SMC, or DSMB, additional details must be provided regarding how monitoring will be performed, the frequency of monitoring, plans for data review, selection of monitors, etc.)

ASSESSING ADVERSE EVENTS:

Monitoring for Adverse Events (AE) will be conducted in real-time by the P.I. and the Research Coordinator. The P.I. will determine the severity of the adverse events, the relationship of the event to the study drug and decide the course of action for the study participant.

Patients are monitored for the development of adverse events by assessing: (check all that apply)

- Laboratory results, specify _____
- Physical exam, specify _____
- Review of medical records, specify _____
- Patient diaries, specify _____
- Other, specify _____

- AEs will be graded according to _____ (i.e. NCI's Common Toxicity Criteria II (CTC II) or other grading scales as appropriate).
- The investigator will determine the relationship of toxicity to test drugs as not related, possibly related, probably related or definitely related using standard criteria. All grades of toxicity will be recorded on the case report forms.

ADVERSE EVENT REPORTING:

The accompanying clinical protocol details the definitions and reporting requirements for adverse and serious adverse events. (If this information is not detailed in the clinical protocol, it must be included in DSMP. The investigators are strongly encouraged to have complete AE information in the clinical protocol. Appendix B of this document provides definitions of AEs and SAEs, unanticipated AEs and expedited adverse events and NCI and FDA reporting requirements).

In addition, all Serious Adverse Events (SAE), whether or not considered related to the investigational product will be reported by the investigator to the IRB, CTSRMC, and other required committees immediately. A copy of the annual report to the IRB of the study progress, adverse events, and serious adverse events will be copied to the CTSRMC.

EVIDENCE OF TRAINING IN HUMAN SUBJECT RESEARCH

- All research personnel associated with this study have completed the University of Pennsylvania's Patient Oriented Research Training Program or the NIH patient oriented research training program.

I have read the UPCC CTSRMC Data Safety and Monitoring guidelines and I agree to adhere to the terms specified above.

PI's Signature

Date