**Data and Safety Monitoring Plan template**

Study Title: <<*insert*>>

Principal Investigator: <<*insert name, title(s)*>>

**BRIEF STUDY OVERVIEW**

<<*Insert a brief description/abstract of the study here.*>>

**OVERSIGHT RESPONSIBILITIES**

Day-to-day oversight of the trial is provided by the Principal Investigator (PI), Dr. <<*insert PI last name*>>. Along with <<*insert names of additional investigators who will be actively involved in the conduct of the study*>>, Dr. <<*insert PI last name*>> assures that informed consent is obtained prior to performing any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan. Drs. <<*insert PI last names plus co-investigators’ names*>> review all study data and any adverse events (AEs) real-time, and report all AEs to the <<*insert as appropriate:* Medical Monitor, Data Monitoring Committee (DMC) chair, sponsor>> and IRB according to the approved DSMP.

Monitor

Monitoring for the study is provided by <<*insert name the organization, for example:* the ITHS Safety Monitoring program>>, including regular data monitoring at the site and regular review by <<*insert as appropriate:* the ITHS Medical Monitor, ITHS DMC, NIH DMSB, sponsor internal safety team>>.

**MONITORING PROCEDURES**

The <<*insert monitoring body, for example:* Medical Monitor, DMC>> reviews study conduct (<<*specify what will be included in reports to the monitoring body:* accrual, drop-outs, protocol deviations>>) and AEs in aggregate on a <<*provide time interval, for example:* weekly, monthly, quarterly, semi-annual, annual>> basis. The <<*insert monitoring body listed above*>> reviews serious adverse events (SAEs), <<*if applicable:* dose-limiting toxicities>>, and <<*list other specific intervention complications*>> in real-time. <<*If applicable, add any other additional reviews the monitoring body will do.*>>

Study data are provided to the <<*insert monitoring body listed above*>> prior to each <<*insert time interval listed above*>> review <<and *if applicable,* *describe additional monitoring planned*). Data reports are prepared by the <<*insert party responsible for putting together these reports, for example:* study statistician>>.

**MONITORING REPORT**

The <<*insert monitoring body listed above*>> provides a written report to the study team with recommendations for study modification, study continuation/discontinuation as relevant.

The study team is responsible for forwarding the report to the IRB.

**COLLECTION AND REPORTING OF SAEs AND AEs**

For this study, the following standard AE definitions are used:

**Adverse event:** Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure.

**Serious Adverse Event:** Any AE that results in any of the following outcomes:

* Death
* Life-threatening
* Event requiring inpatient hospitalization or prolongation of existing hospitalization
* Persistent or significant disability/incapacity

AEs are graded according to the following scale <<*use scale below or whatever scale is proposed for the study*>>:

**Mild:** An experience that is transient, & requires no special treatment or intervention. The experience does not generally interfere with usual daily activities. This includes transient laboratory test alterations.

**Moderate:** An experience that is alleviated with simple therapeutic treatments. The experience impacts usual daily activities. Includes laboratory test alterations indicating injury, but without long-term risk.

**Severe:** An experience that requires therapeutic intervention. The experience interrupts usual daily activities. If hospitalization (or prolongation of hospitalization) is required for treatment it becomes an SAE.

The study uses the following AE attribution scale <<*use scale below or whatever scale is proposed for the study*>>:

**Not related:** The AE is clearly not related to the study procedures (i.e., another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).

**Possibly related:** An event that follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.

 **Related:** The AE is clearly related to the study procedures.

AEs are identified <<*describe how AEs will be captured, for example:* during hospital admission when potential AEs are assessed through a review of the hospital chart on a daily basis and a physical examination of the subject. After discharge, AEs are assessed at time of study follow-up visits.>>

SAEs and specific procedure-associated AEs are reported to the <<*insert monitoring body listed above*>> within 24 hours. In addition, all AEs are reported according to the <<*insert name of IRB overseeing the study*>> AE reporting guidelines.

**MANAGEMENT OF RISKS TO SUBJECTS**

Expected AEs

Expected AEs associated with the <<*insert:* drugs being used in the study and study procedures) include:

* <<*List expected toxicities of the study drugs/procedures*>>

AE Management

<< *If applicable, insert description of any specific management plans for expected AEs.*>>

Dose Escalation and Dose-Limiting Toxicities

<<*If applicable, insert description of plan for dose escalation and what will be considered dose-limiting toxicities.*>>

**DATA ANALYSIS PLANS**

<<*Describe the planned interim analysis for efficacy, safety, or both. Specify the safety parameters that will be reviewed (for example: expected AEs in aggregate, all SAEs, and dose-limiting toxicities). Describe study stopping rules, if applicable.*>>

**PLAN FOR DATA MANAGEMENT**

The <<*insert data monitoring body listed under “Monitoring” above*>> reviews study data on a <<*provide time interval:* monthly, quarterly, semi-annual, annual>> basis. <<*If applicable:* In addition, a site monitor does an initial site visit for training and a close out visit at the end of the study. The site monitor reviews all regulatory documents for compliance and study documents for data accuracy and completeness.>>

Confidentiality throughout the trial is maintained by <<*insert description of study-specific confidentiality procedures*>>.