**KESSLER FOUNDATION**

**INSTITUTIONAL REVIEW BOARD**

**SERIOUS Adverse Events Report Form**

**IRB #**

**Study title:**

**REPORT submitted**:

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Principal Investigator (printed name) Signature**

**Phone Email**

**Address**

**REPORTING REQUIREMENTS FOR SERIOUS ADVERSE EVENTS ON #5010b**

**Investigators must report ALL Serious Adverse Events (expected/unexpected; associated or not associated with the research intervention) to the IRB Administrator, Federal and/or funding agencies or other sponsors as required**

1. Within 48 hours (i.e. within two business days) of the event’s report to the study team using

the SERIOUS Adverse Events REPORT form.

1. Within 24 hours (i.e. within one business day) of the event’s report to the study team for

deaths.

**REPORTING REQUIREMENT FOR ALL ADVERSE EVENTS ON #5010a “ADVERSE EVENTS**

**LOG FORM”**

**Procedure to ascertain new adverse events at each subject visit/contact:**

During each subject visit, the principal investigator or his/her designee must ascertain if the subject has experienced an adverse event (AE), and record the event on the Adverse Events LOG form. ***The Adverse Events LOG is a cumulative record of all adverse events for the study and is organized by subject: mild, moderate, serious; expected and unexpected; associated or unassociated with the study intervention; local site or other site of multi-center study****.* Principal investigators must submit the Adverse Events LOG(s) to the IRB on an annual basis during a protocol’s continuing review and with its Termination Report.

**I. Description of Serious Adverse Event**

Date of SAE report to study team:

Subject #: Subject age:  Subject Gender: [ ] M [ ] F

## Location of SAE:

## Date of onset:

## Date of Resolution: SAE Continuing [ ]

Has the same SAE occurred previously? [ ] No [ ] Yes Explanation

Adverse Event resulted in (check all appropriate items):

[ ]  Death Date of Death:

[ ]  Life threatening experience

[ ]  Persistent or significant disability/incapacity or congenital anomaly/birth defect

[ ]  Hospitalization or prolongation of existing hospitalization

[ ]  Medical events which jeopardize the patient or subject and may require medical or surgical

 intervention to prevent one of the outcomes listed above

Description of adverse event:

**II. Determination of the study relatedness or causality of SAE**

In determining whether the SAE is study related, the PI should consider the following:

* Could the event have been produced by the participant’s clinical state?
* Does the event have a temporal relationship to the intervention?
* Could the event have been caused by clinical interventions other than the study intervention?
* Does the event follow a known pattern of response to the intervention?
* Does the event disappear or decrease with reduction in dose or cessation of the intervention?
* Does the clinical member of the study team believe the event to be study related?

## Was the adverse event related to research procedures?

[ ]  Not related (clearly due to extraneous causes, e.g. underlying disease, environment)

[ ]  Unlikely (low probability that study intervention caused SAE)

[ ]  Probably (more likely than not that study intervention caused SAE)

[ ]  Causative (highly probable that study intervention caused SAE)

[ ]  Inconclusive (study intervention may be related to SAE but not enough information to establish

>50% probability)

**III. Reporting of Serious Adverse Event**

A reasonable effort must be made to secure a copy of any relevant autopsy report and/or hospital medical records, which should be submitted for SAEs; files should be documented for the autopsy report/medical records request(s).

[ ]  Autopsy report *attached*

[ ]  Autopsy report not available because

[ ]  Hospital medical records *attached*

[ ]  Hospital report not available because

Copies of any SAE Report forms provided by the Investigator to the sponsor/FDA or other regulatory agencies should also be submitted simultaneously to the IRB.

[ ]  Sponsor/FDA/regulatory agency report *attached*

*[ ]* Not applicable or not required

*The EVENT number refers to the log number for the event – all events are cumulatively numbered for the protocol.*

For this protocol, this is EVENT#

**IV. Treatment provided to Subject as a result of the SAE**

Treatment provided: **[ ]** None [ ] Hospitalized [ ] Medical care provided: \_\_\_\_

Outcome: **[ ]** Recovered [ ] Recovered w/sequelae [ ] Ongoing [ ] Died [ ] Unknown

Subject involvement in study [ ]  continued [ ]  discontinued [ ]  delayed

 [ ]  other Explanation:

**V. Protocol revisions and changes**

Changes in Study Protocol as a result of SAE

**[ ]** NoChange [ ]  Study Protocol Interrupted [ ]  Study Protocol Discontinued

Is a change to the protocol (or project description) or Consent form necessary to reduce or eliminate risk to subjects?

[ ]  Yes – attach revised protocol and/or consent form (changes should be highlighted)

[ ]  No Explanation:

Is it necessary to inform subjects/legally authorized representatives, who have already consented to participation in the study, of the adverse event?

[ ]  Yes

[ ]  No Explanation: