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.
(2) 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

☐ No Change ☐ 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: _____