KESSLER FOUNDATION
INSTITUTIONAL REVIEW BOARD

UNEXPECTED 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 to the IRB Administrator all UNEXPECTED adverse events of MODERATE OR GREATER SEVERITY associated with the study intervention.

(1) Unexpected adverse events of moderate severity associated with the study intervention must be reported within five business days of the event's report to the study team using the **UNEXPECTED Adverse Events REPORT form**.

(2) Unexpected adverse events that are serious must be reported within 24-48 hours (i.e. within one-two business days) of the event's report to the study team using the Serious Adverse Events REPORT form.

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.

UNEXPECTED ADVERSE EVENTS REPORT FORM
UNEXPECTED AEs of MODERATE or GREATER SEVERITY ASSOCIATED WITH STUDY INTERVENTION

Date of AE Report to Study Team:

Date of Onset: _____ Date of Resolution:

Subject #: _____ Subject age: _____ Subject Gender: ☐M ☐F

Check two: ☐ Mild ☐ Moderate and ☐ Expected ☐ Unexpected

Description of AE:

Location of AE:

Study-Relatedness:

- **Not related (clearly due to extraneous causes, e.g. underlying disease, environment)**
- **Unlikely (low probability that study intervention caused AE)**
- **Probably (more likely than not that study intervention caused AE)**
- **Causative (highly probable that study intervention caused AE)**
- **Inconclusive (study intervention may be related to AE but not enough information to establish >50% probability**

☐Not Related ☐ Unlikely ☐ Probably-Associated ☐ Causative ☐ Inconclusive

Treatment provided: ☐ None ☐Hospitalized ☐Medical care provided:

Outcome: ☐ Recovered ☐ Recovered w/sequelae ☐ Ongoing ☐ Died ☐ Unknown

Changes in Study Protocol as a result of AE

☐ 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: ____

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