

**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: \_\_\_\_\_

–