**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: |