**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.

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| UNEXPECTED ADVERSE EVENTS REPORT FORMUNEXPECTED 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 [ ] FCheck two: [ ]  Mild [ ]  Moderate and [ ]  Expected [ ]  UnexpectedDescription 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 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

[ ] Not Related [ ]  Unlikely [ ]  Probably-Associated [ ]  Causative [ ]  InconclusiveTreatment provided: [ ]  None [ ] Hospitalized [ ] Medical care provided: Outcome: [ ]  Recovered [ ]  Recovered w/sequelae [ ]  Ongoing [ ]  Died [ ]  UnknownChanges in Study Protocol as a result of AE[ ]  No Change [ ]  Study Protocol Interrupted [ ]  Study Protocol DiscontinuedIs 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:   |