# KESSLER FOUNDATION

04.2014

**INSTITUTIONAL REVIEW BOARD**

**Adverse Events LOG**

**IRB #***\_\_\_\_\_\_\_\_\_*

**Study title:**

**LOG submitted**: *\_\_ \_\_\_\_*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator (printed name) Signature**

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_*

**Phone Email**

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_*

**Address**

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**REPORTING REQUIREMENT FOR ALL ADVERSE EVENTS ON #5010a**

**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.

1. A separate Adverse Events LOG form is to be provided for all AE reports for each subject

(2) A package of all AE reports for the study is to be presented with the protocol’s continuation review and

termination report

(3) This cover sheet should accompany the submission of the Adverse Events LOG to the IRB

**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 REQUIREMENTS FOR UNEXPECTED ADVERSE EVENTS ON #5010c**

**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.

1. 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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ADVERSE EVENTS LOG for Protocol #*\_\_\_\_\_\_\_\_\_\_\_* Page** *\_\_\_\_\_\_\_\_\_\_\_*  KESSLER FOUNDATION ADVERSE EVENTS LOG | | | | | | | **Subject #** *\_\_\_ \_***Subject Initials *\_\_ \_* Male**  **Female  Age** *\_ \_ \_\_* | | | |
| **Adverse Event** | **Duration** | | **Duration** | **Was Event Serious** | **Severity** | **Study Drug** | | **Action Taken** | **Relation to Study Drug/**  **Intervention** | **Outcome** |
| check if none for this subject | Date of Onset | Date of Resolution | | 1=Yes\*  0=No | 1=Mild  2=Moderate  3=Severe | 1=No Change  2=Dose Decrease  3=Dose Increase  4=Interrupted  5=Discontinued | | 1=None  2=Medication/treatment given  3=Hospitalized  4=Other (specify) | 1=None  2=Unlikely  3=Possible  4=Probable | 1=Recovered  2=Recovered w/sequelae  3=Ongoing  4=Died  5=Unknown |
| AE desc. | mm/dd/yy | mm/dd/yy | | Choose one | Choose one | Choose one | | Check all that apply | Choose one | Choose one |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |
|  |  |  | | Yes  No | Mild  Moderate  Severe | 1 4  2 5  3 | | 1 2 3  4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 1 3  2 4 | 1 4  2 5  3 |