KESSLER FOUNDATION
INSTITUTIONAL REVIEW BOARD

Adverse Events LOG

IRB #_____

Study title:

LOG submitted: _____

Principal Investigator (printed name) _____ **Signature**

Phone _____ **Email**

Address _____

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.

(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

KESSLER FOUNDATION ADVERSE EVENTS LOG

ADVERSE EVENTS LOG for Protocol #____________ ____________					Page	Subject # ____________ Age ______	Subject Initials ________	Male ☐ Female ☐
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