THE NEBRASKA METHODIST HOSPITAL 8303 DODGE STREET OMAHA, NEBRASKA 68114 402-354-4000

Institutional Review Board
Adverse Event/Safety Reports

Use of Form: This form is to be used by the principal investigator of a study previously approved by the IRB, to report to the IRB when an adverse event report or safety report has been issued regarding the study.

BEFORE SUBMITTING THIS FORM, THE SUBMITTING INVESTIGATOR MUST REVIEW THE ADVERSE EVENT REPORT, AND CERTIFY THAT IT FALLS WITHIN ONE OF THE FOLLOWING THREE CATEGORIES (check ONE):

☐ **This is a report of an internal adverse event (an adverse event occurring at Methodist Hospital).**

☐ **The report meets all of the following criteria:**

- **This is an OPEN study at Methodist Hospital or it has been closed less than 30 days, or there are still subjects receiving therapy at Methodist Hospital; and**
- **The adverse event reported is unexpected or occurring at an unexpected frequency; and**
- **The adverse event reported is serious; and**
- **The sponsor and the submitting investigator assess the adverse event as probably or definitely related to the study drug in question.**

☐ **The report does not meet the criteria outlined above.**

IF THE LAST BOX IS CHECKED, THE REPORT WILL BE MAINTAINED ON FILE BY THE IRB OFFICE BUT WILL NOT BE SUBSTANTIVELY REVIEWED BY THE IRB.

1. **Title of Study:**

2. **Principal Investigator's Name**:

3. **Date of this Report:**

4. **Number of Subjects in Study, to Date:**

   Locally (under NMH IRB Authority):

   Nationally (if known, or estimate):

5. Date(s) of Adverse Event/Safety Reports:

6. Does the Report Change the Risk - Benefits Ratio for the Subjects? ◯ **No** ◯ **Yes**

If yes, how:

7. Do You Recommend Changes to the Informed Consent Form? ◯ **No** ◯ **Yes**

If yes, explain:

8. Do You Recommend That Currently Enrolled Subjects be Contacted With Information Regarding These Reports? ◯ **No** ◯ **Yes**

If yes, what is your plan to contact them:

9. PLEASE ATTACH COPIES OF THE ADVERSE EVENT/SAFETY REPORT(S) AND THE CURRENT INFORMED CONSENT FORM.

Signature of Principal Investigator:

Date Submitted:

A typed name in the above signature field confirms you are the Principal Investigator submitting this Adverse Event/Safety Reports form.

Submit