1. When to Use This Form

Please use this form to submit "reportable," "local" adverse events.

Do NOT submit "non-reportable" or "external" adverse events on this form; use a different Form 4 for those events.

"Local" means the adverse event occurred at a UTHSC IRB-approved site for this study/project.

The PI determines whether the adverse event is "reportable" based on the UTHSC IRB's reporting requirements below.

UTHSC IRB Adverse Event Reporting Requirements

A. Problems or adverse events at local sites that MUST BE reported:
1. all "unanticipated problems" other than adverse events (report on Form 4c)
2. local adverse events (report on Form 4a) if the principal investigator determines the events are:
   a) unexpected AND
   b) serious AND
   c) possibly, probably, or clearly related to the research intervention

(Mouse over the question mark icon in the right margin and click on "terminology for unanticipated problems, including adverse events" for definitions.)

B. Time frames for reporting problems, including adverse events, at all local sites:
1. report any death that meets the reporting requirements within 24 hours of its occurrence
2. report within 5 working days of its occurrence:
   a) any adverse event (other than death) at any local site that meets the reporting requirements
   b) any other problem at any local site that meets the reporting requirements

NOTE: Please use Form 4d when you have adverse events that do NOT meet the UTHSC IRB's reporting requirements, but when your sponsor or institution (such as Methodist or Le Bonheur) would like you to submit them anyway. If you are conducting a research project at a Methodist or Le Bonheur facility, Methodist & Le Bonheur Administration requires that all "non-reportable" adverse events (internal and external) be submitted for review via Form 4d.

2. General Information

Study/Project Information (Read Only)

Study/Project Title

Principal Investigator

Department Name

Serious Adverse Event

Please provide information on the following aspects of this local serious adverse event:

* 1. Please indicate if this is an initial or a follow-up report:

If this is a follow-up report, please click the green bar below. After you click the green bar, make sure the check mark shows in the check box on the far left-hand side of the screen before you click "Save Attachments."

Click here to select the Form 4a: Reportable Local Adverse Events we are associating to this follow-up.

* 2. Please provide the reference number or code that links the adverse event to its documentation (such as an AE# or SAE #):

If there is no number/code, please type "NA."

* 3. The Principal Investigator has determined that this event is:

For the definition of "serious" please click on the question mark icon in the right margin.

- [ ] life-threatening
- [ ] required in-patient hospitalization
- [ ] prolonged an existing hospitalization
- [ ] created persistent or significant disability or incapacity
- [ ] resulted in a congenital anomaly or birth defect
- [ ] caused death
- [ ] required medical or surgical intervention to prevent one of the outcomes noted above

* 4. Please indicate if this event was or was not expected:

- ○ Expected
- ○ Not Expected

* 5. In the opinion of the Principal Investigator, the injury/event was:

- ○ POSSIBLY related to the use of the research article, device or procedure.
- ○ PROBABLY related to the use of the research article, device or procedure.
- ○ CLEARLY related to the use of the research article, device or procedure.

* 6. Subject code that links the AE to the subject (for example, Subject ID #):

If there is no subject code, please type in "n/a."

* 7. In a few words, describe the nature of this event:

For example: kidney failure, heart failure, sepsis, arrhythmia, respiratory failure, accidental injury, etc.
Note: on the next screen you will be given more space to describe the event.

* 8. The date this form is completed (read only):

this date will be filled in automatically

* 9. Please provide the date of the injury/event:

* 10. Was the study/project intervention stopped or delayed?

- Yes. The study/project intervention was stopped or delayed.
- No. The study/project intervention continued. It was not stopped or delayed.
- No. The study/project intervention was already complete at the time of this event.
- Not applicable.

11. If applicable, date study/project intervention stopped or delayed:

* 12. If stopped or delayed, was the study/project intervention (re)started?

- Yes. The study/project intervention was restarted.
- No. The study/project intervention was not restarted.
- Not Applicable.

13. If applicable, date (re)started:

3. Description of SAE

* Please describe the adverse event that prompted this report.

Your discussion of the adverse event should address the following points: (1) describe the adverse event; (2) explain what interventions were undertaken to address it; (3) what outcome occurred; (4) explain the reasons that support your judgment of whether the adverse event is related to study/project procedures; and (5) provide your assessment of whether the event is consistent with the risk profile of the study/project procedures or is genuinely unexpected.

4. Impact of SAE

Do you recommend a change to protocol procedures, the risk-benefit assessment or the consent form relative to the serious adverse event reported above?

* Protocol Procedures:

- ○ Changes to protocol procedures are recommended.
- ○ No changes to protocol procedures are recommended.

* Risk-Benefit Assessment:

- ○ Changes to the risk-benefit assessment are recommended.
- ○ No changes to the risk-benefit assessment are recommended.

* Consent Form:

- ○ Changes to the consent form are recommended.
- ○ No changes to the consent form are recommended.

* Please discuss the changes that are recommended. If no changes are recommended, briefly explain why they are not necessary.

Please note, if changes are to be made, the changes must be submitted on a Form 2.

5. Attachments

Please attach the appropriate ER or Progress Notes (if available) and additional related documents. After you click the green bar, make sure the check mark shows in the check box on the far left-hand side of the screen before you click "Save Attachments."

When you have finished attaching the requested document(s), please click on "Save and Continue to the Next Section."

6. Close Form

The following text box is provided in the event that you need to share any additional information regarding your project with the Review Board.

Sign and Submit