1. When to Use this Form:

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

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

"External adverse events" are events that occur at another multi-center site where subjects are enrolled by investigators from a different institution. The sponsor of the study/project will send reports of external adverse events to the local PI. These reports are usually called IND Safety reports or Medwatch reports.

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

UTHSC IRB Adverse Event Reporting Requirements

1. External adverse events must be reported if the principal investigator determines the events to be:
a) unexpected AND
b) serious AND
c) possibly, probably, or clearly caused by the research intervention

2. Time frame for reporting external adverse events:
within 10 working days of receipt of the report by the local investigator.

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

Study/Project Title

Principal Investigator

Department Name

External Adverse Event(s)

Please attach each report of an external adverse event. 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 on "Add a new row" to provide information on the following aspects of each external adverse event:

Add a new row | Copy existing row(s) | Delete selected row(s)

	Initial / Follow-up	Subject Code	Mfr. Report #	Nature of Event	Relation to Research	Seriousness	Expected / Unexpected	Date of Injury	Report Attached
No record has been added									

3. Impact of Adverse Event(s)

Do you recommend a change to protocol procedures, the risk-benefit assessment or the consent form relative to the external adverse event(s) 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.

4. 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.

You have completed the Report of External AE's.

Please click the "Sign and Submit" button.

Sign and Submit	