UTK Instructions:

Use this form to submit Reportable Information, such as Unanticipated Problems including Reportable Adverse Events, Major Protocol Deviations, and Protocol Waivers.

revised (07-21-2014)

General Information (Read Only)

IRB Number:

Study/Project Title:

Principal Investigator:

Department Name:

*Check the type of problem/issue:

- [X] Local reportable adverse event or unanticipated problem
- [X] External reportable adverse events or unanticipated problem
- [X] Major protocol deviation or violation
- [X] Protocol Waiver Request
- [X] Problem identified in audit, inspection, or inquiry by a federal agency (e.g., FDA Form 483, OHRP report, etc.)
- [X] Problem identified in audit, inspection, or inquiry by a study site or institution (other than the UTK IRB)
- [X] Suspension or premature termination of the study by the sponsor, investigator, or institution
- [X] State medical board action
- [X] Loss of investigator's credentials at institution

(505) Adverse Event Criteria

Mouse over green text for definitions

The investigator has determined that the adverse event/ unanticipated problem is:

*** Unexpected**

[X] Yes [X] No

*** Serious**

[X] Yes [X] No

*** Possibly, Probably, or Clearly Related to the research intervention**

[X] Yes [X] No

(506) Adverse Event Information

Please click on "Add a new row" to provide information on the following aspects of each adverse event. When you are finished, please click "Save and Continue to the Next Section."

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

	Patient ID # or Mrf. Report #	Nature of Event (s)	Initial/Follow-up	Date of Injury	Date of Report
No record has been added					

(507) Protocol Deviation or Violation Criteria

The investigator has determined that the protocol deviation / violation:

***has harmed or has posed a significant risk of substantive harm to the individual research subject**

☒ Yes ☒ No

***has compromised the scientific integrity of the data collected for the study/project**

☒ Yes ☒ No

***appears to result from willing or knowing misconduct on the part of an investigator or study/project staff**

☒ Yes ☒ No

***appears to involve some other serious or continuing noncompliance with federal, state, or local research regulations**

☒ Yes ☒ No

(510) Local Adverse Event

Serious Adverse Event

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

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

☒

If this is a follow-up report, please click the bar below.

Click here to select the Form 4: Reportable Information: Problems/Deviations 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 #):

☒

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

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

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

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

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

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

[X]

6. 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.

[X]

* 7. The date this form is completed (read only - this date will be filled in automatically):

[X]

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

[X]

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

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

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

[X]

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

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

12. If applicable, date (re)started:

☒

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.

☒

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 also be submitted on a Form 2: Change Request/Amendment.

Then click on "Save and Continue..."

☒

(515) Attachments

Please attach the appropriate ER or Progress Notes (if available) and additional related documents by clicking the bar.

(520) External Adverse Event(s)

Attach External Adverse Event(s)

Please attach each report of an external adverse event by clicking the bar.

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 Examples: kidney failure, sepsis	Relation to Research	Seriousness	Expected / Unexpected	Date of Injury	Report Attached
No record has been added									

(525) 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 also be submitted on a Form 2: Change Request & Amendments.

☒

(530) Protocol Deviation/Violation

Please provide information on the following aspects of this unanticipated problem:
Then click on "Save and Continue..."

* 1. Type of problem:

☒ Protocol Deviation or Violation

☒ Other Problem

* 2. Please indicate whether this is an initial or a follow-up report:

☒

* 3. In a few words, describe the nature of this problem:
For example: study/project drug lost, consent forms stolen, study/project files not secured, laboratory samples mislabeled, etc.

Note: on the next screen you will be given more space to describe the event.

☒

* 4. The date this form is completed (read only - this date will be filled in automatically):

☒

* 5. Onset date:

☒

* 6. Please indicate the current status:

☒ Resolved

☒ Ongoing

7. If resolved, please provide the date resolved:

☒

(535) Description of Problem

*** Please describe the circumstances that prompted this report:**
Then click on "Save and Continue..."

☒

(536) Impact of Problem

***Do you recommend a change to protocol procedures, the risk-benefit assessment assessment, or the consent form relative to the problem 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.

☒ 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 also be submitted on a Form 2: Change Request/Amendment.

☒

(537) Attachments

Please attach all documents relative to this problem by clicking the bar.

(540) Description of Protocol Waiver Request

*** Please describe the circumstances that prompted this report:**
Then click on "Save and Continue..."

(545) Description of Audit, Inspection, or Inquiry by a Federal Agency (e.g., FDA Form 483)

*** Please describe the circumstances that prompted this report, including the beginning and end dates of inspection, time line, cause, actions taken, and any changes made:**
Note: If changes will be required of your study, also submit a Form 2: Change Request/Amendment.

Attachments
Please attach a copy of all reports & correspondence related to the audit, inspection, or inquiry (e.g., FDA Form 482 and 483, Site's Response to the 483, FDA letter responding to the site, FDA Warning Letter, OHRP reports, etc.), by clicking the bar.

(550) Description of Audit, Inspection, or Inquiry by a Study Site or Institution (other than the UTK IRB)

*** Please describe the circumstances that prompted this report, including date of occurrence, time line, cause, actions taken, and any changes made:**
Note: If changes will be required of your study, also submit a Form 2: Change Request/Amendment.

Attachments
Please attach all documents & correspondence related to the audit, inspection, or inquiry by clicking the bar.

(553) Description of Suspension or Premature Termination of the Study by the Sponsor, Investigator, or Institution

*** Please describe the circumstances that prompted this report, including date of occurrence, time line, cause, actions taken, and any changes made:**
Note: If changes will be required of your study, also submit a Form 2: Change Request/Amendment.

Attachments
Please attach all documents related to the suspension or premature termination by clicking the bar.

(555) Description of State Medical Board Action

*** Please describe the circumstances that prompted this report, including date of occurrence, time line, cause, actions taken, and any changes made:**
Note: If changes will be required of your study, also submit a Form 2: Change Request/Amendment.

Attachments
Please attach a copy of state medical board licensing documentation (e.g. physician's (suspended) license, a physician profile, or a physician licensing profile indicating a disciplinary, or even a non- disciplinary action)

by clicking the bar.

(560) Description of Loss of investigator Credentials at Institution

*** Please describe the circumstances that prompted this report, including date of occurrence, time line, cause, actions taken, and any changes made:**
Note: If changes will be required of your study, also submit a Form 2: Change Request/Amendment.

Attachments
Please attach all documents related to the loss of credentials at the institution by clicking the bar.

(565) Adverse Event Not Reportable

Because your adverse event/ unanticipated problem does not meet all 3 reporting criteria, it does not need to be submitted to the UTK IRB for review.

Click the tab "Entire View of Form." Next, click "Print Friendly" button in upper right corner and keep a copy for your records. This form 4 will remain a draft because you cannot submit it to the IRB from this screen. If you have further questions, please call the IRB office at (865) 974-7697.

Thank you,
UTK IRB Administration

(570) Protocol Deviation / Violation Not Reportable

Because your protocol deviation / violation does not meet any of the reporting criteria, it does not need to be submitted to the UTK IRB for review.

This form 4 will remain a draft because you cannot submit it to the IRB from this screen. If you wish, you may back out of the form and delete this draft from your Form 4 folder in iMedRIS. If you have further questions, please call the IRB office at (865) 974-7697.

Thank you,
UTK IRB Administration

Sign and Submit

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

Please click the "Sign and Submit" button."

Sign and Submit

Form Complete

Click form complete if this is a revision to the previously submitted form if not click the sign and submit button in the previous section.

Form Completed Click here to close the Form