Office of Research and Sponsored Programs
Sam Houston State University
903 Bowers Blvd, PO Box 2448
Huntsville, TX 77341
Phone: 936.294.3621
Fax: 936.294.3622

ADVERSE EVENT REQUIRING PROMPT REPORTING TO THE PHSC

This form should only be used to report Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) or other events that require prompt reporting according to the SHSU IRB Standard Operating Procedure #6 (see section II below).

SECTION I: RESEARCH PROTOCOL INFORMATION

Current Date: Protocol Number:

1. Research Title:

2. Principal Investigator

Name University Status/Title

Department College

Phone Number Email Address

3. Supervising Faculty - required if PI is a student

Name University Status/Title

Department College

Phone Number Email Address

Contact Information: Someone other than the PI who may be contacted regarding this report (i.e., Co-PI, Study Coordinator, Nurse, Physician, etc.)

Name Phone Email

If the event requires a change to the protocol and/or consent document, is an Amendment attached?

☐ Yes ☐ No ☐ Pending

SECTION II: TYPE OF EVENT (CHECK ALL THAT APPLY)

☐ Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO) [see IRB SOP #6, section 4.02.a]

☐ Breach of Confidentiality (e.g., computer theft, invasion of privacy, unauthorized use of PHI, etc.)

☐ Events requiring prompt reporting according to the protocol, sponsor, or funding agency (PIs should also be aware of state and local mandatory reporting laws (such as for child abuse, suicidal ideation, etc.))

☐ New information indicating an unexpected change in risks or potential benefits (e.g., literature/scientific reports or other published findings)

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☐ Protocol deviations, violations, or other accidental or unintentional changes to the protocol or procedures involving risks or with potential to recur

☐ Emergency protocol deviation made to eliminate apparent immediate hazard to a research participant

☐ Subject complaints indicating an unanticipated risk or complaints that cannot be resolved by the research staff

☐ Unapproved changes made to the research to eliminate an apparent immediate hazard to a subject

☐ Other problem or finding (e.g., loss of study data or forms, a minor subject becomes an adult while participating in the research, a subject becomes a prisoner while participating in the research, etc.) that an investigator or research staff member believes could influence the safe conduct of the research.

SECTION III: EVENT INFORMATION

1. Date of Event: Date PI Notified of Event

2. Where was the subject enrolled in the research?

☐ SHSU Campus ☐ SHSU Off-Campus—Identify off-campus location:

☐ Non-SHSU Site—Identify site:

3. Event Report: ☐ Initial Report ☐ Follow-up Report #

4. Provide a brief description of the event being reported and how it impacted the safety or welfare of subjects of others (attach supplemental materials as necessary):

5. Research Status—the research subject's status following event occurrence:

☐ Continued research intervention/interaction ☐ Stopped research intervention/interaction

☐ Continued research—follow-up only ☐ Subject withdrew from further participation

☐ Already completed research ☐ PI withdrew subject from further participation

6. Number of subjects currently enrolled at SHSU: and/or Multi-center Sites:

7. Research recruitment (at SHSU or at a site under the SHSU PHSC's jurisdiction) is:

☐ On-going ☐ Completed ☐ Suspended

8. Research interventions/interactions involving other subjects are:

☐ On-going ☐ Completed ☐ Suspended

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SECTION IV: ASSESSING THE EVENT

1. If this event or information represents an UPIRSO, explain why:

2. Is this event, including the severity and frequency of the event, consistent with the information (i.e., protocol, literature, consent, etc.) provided to the IRB? ☐ Yes ☐ No

If no, explain why not:

3. Is this event, including the severity and frequency of the event, consistent with the information provided to the subject?
☐ Yes ☐ No

If no, explain why not:

4. Did the event compromise the validity or integrity of the study data? ☐ Yes ☐ No

If yes, please explain:

SECTION V: ACTIONS TO BE TAKEN BY THE PI

☐ No action is planned; no changes needed to the research protocol and/or consent process

☐ Modification(s) of the research protocol or procedures**

☐ Modification(s) of the consent process or consent form**

☐ Providing additional information to current research participants (required when such information may relate to their willingness to continue in the research) **

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- ☐ Providing additional information to past research participants**
- ☐ Reconfirming consent of current research participants**
- ☐ Requiring additional follow-up/monitoring for current and/or past research participants**
- ☐ Monitoring of the research (including audits) or consent process
- ☐ Education or mentoring for the principal investigator and/or research staff
- ☐ Additional reporting, including modification of the continuing review schedule
- ☐ Requiring additional resources to support the investigator's research activities
- ☐ Placing limitations (e.g., restriction to co-investigator status) on the investigator's research activities or use of research data
- ☐ Suspending or terminating the research***
- ☐ Referral to other appropriate university process (e.g., the Provost and Vice President for Academic Affairs, as outlined in Academic Policy Statement 920808)

**Requires the submission of an amendment to the PHSC for approval. Complete and provide the amendment request form along with any associate document(s) for all proposed changes and communications
***May prompt additional reporting requirements—refer to SHSU policy on Institutional Reporting Requirements

SECTION VI: ADDITIONAL REPORTING REQUIREMENTS
To whom has the event been reported?

- ☐ Research sponsor/coordinating site — Date Reported:
- ☐ Other collaborators — Date Reported:
- ☐ SHSU Administration — Date Reported: