

1. GENERAL

- 1.01 Federal regulations require the University to have written procedures for insuring that unanticipated problems involving risks to subjects or others are promptly reported to the IRBs, appropriate institutional officials, and federal agencies. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
- 1.02 Unanticipated problems can occur in any type of research and may include occurrences such as adverse events, subject complaints, protocol deviations, and other untoward events involving risk. Events requiring prompt reporting by investigators and research staff may involve physical, psychological, social, legal, or economic harms. Unanticipated problems may come to the attention of the IRB from a number of sources including Event Report Forms submitted by the researcher, an IRB member, or a study participant who contacts the Research Compliance Administrator (RCA).

2. PURPOSE

The purpose of this SOP is to provide Investigators with procedures to follow when reporting unanticipated problems with their study involving human subjects to the IRB.

3. DEFINITIONS

Go to the [Glossary](#) for definitions.

4. EVENTS REQUIRING PROMPT REPORTING

- 4.01 Investigators and research staff are responsible for reporting to the IRB unanticipated problems involving risks to subjects or others. Such reports may include adverse events, subject complaints, protocol deviations, and other untoward events involving risk. The convened IRBs are responsible for making the final determination that a reported event is an unanticipated problem involving risks to subjects or others.

- 4.02 The following events may represent unanticipated problems involving risks to subjects or others and thus should be promptly reported:
- a. Adverse events or injuries that suggest the research places subjects at a greater risk of psychological harm than was previously known or recognized, are unexpected, and are related to the research
 - (1) Any adverse events, which are considered to be life threatening or extreme (such as would require hospitalization, for example) should be reported to the IRB within 24 hours of the event
 - (2) The death of a research subject must be reported by telephone to the IRB within 24 hours, and a written report follow within 5 days
 - b. Breaches of confidentiality involving risks to subjects or others
 - c. Events requiring prompt reporting according to the protocol, sponsor, or funding agency [PIs should also be aware of state and local mandatory reporting laws (i.e., for child abuse, suicidal ideation, etc.)]
 - d. New information indicating an unexpected change in risks or potential benefits (e.g., literature/scientific reports or other published findings)
 - e. Protocol deviations, violations, or other accidental or unintentional changes to the protocol or procedures involving risks or with the potential to recur
 - f. Subject complaints indicating an unanticipated risk, or complaints that cannot be resolved by the research staff
 - g. Unapproved changes made to the research to eliminate an apparent immediate hazard to a subject
 - h. Other problem or finding (e.g., loss of study data or forms, a subject becomes a prisoner while participating in research, etc.) that an investigator or research staff member believes could influence the safe conduct of the research
- 4.03 Both internal events and external events that may represent unanticipated problems involving risks to subjects or others should be promptly reported. For a flowchart of event reporting requirements, see [Figure 1](#).

5. TIMEFRAME FOR REPORTING

- 5.01 The events described above should be reported to the IRB using the Event Reporting Form within 5 days of the investigator's or research staff member's learning of the event, except as noted in 5.02 and 5.03.
- 5.02 Events resulting in harm or reasonable likelihood of harm to subjects should be reported to the IRB as soon as possible and no later than within 24 hours.
- 5.03 Events resulting in temporary or permanent interruption of study activities by the investigator or sponsor to avoid potential harm to subjects should be reported to the IRB within 48 hours whenever possible.
- 5.04 All internal and external events that may represent unanticipated problems involving risks to subjects or others should be promptly reported (as described above), regardless of whether they occur during or after the study, or involve a subject who has withdrawn from or completed study participation. If changes to the research or consent process are proposed as a result of the event, or if additional information will be provided to current and/or past participants, an amendment request must also be submitted for IRB review.

6. EVENTS NOT REQUIRING PROMPT REPORTING

- 6.01 Potential risks and adverse events that may be reasonably anticipated (i.e., "expected") should be described in the informed consent process/form. The following are examples of events that do not require prompt reporting to the IRB by investigators and/or research staff:
 - a. Adverse device effects that are non-serious, anticipated, or unrelated to the research
 - b. Adverse events or injuries that are non-serious, expected, or unrelated to the research
 - c. Deaths not attributed to the research, e.g., from "natural causes," accidents, or underlying disease and the investigator has ruled out any connection between the study procedures and the participant's death

- d. Protocol deviations or violations unlikely to recur or not involving risks to subjects
 - e. Subject complaints that were resolved by the researcher or complaints not involving risks
 - f. Problems or findings not involving risk (unless the investigator or research staff member believes the information could affect participants' willingness to continue in the research)
- 6.02 Related internal and external events involving risk but not meeting the prompt reporting requirements will be reported to the IRB in summary form at the time of continuing review.
- 6.03 External events that do not meet the reporting requirements (e.g., not related or not involving risk) and that are not relevant to the protection of participants in Sam Houston State University research should not be reported. Investigators should retain copies of all individual Event Report Forms on file.

7. REVIEW PROCESS

Event reports and accompanying information will be screened for completeness by the ORSP's RCA (or Chair's designee), who will make an initial determination about whether the event represents a possible unanticipated problem involving risks to subjects or others, and may request additional information from the researcher. Reports of events determined during screening to represent possible unanticipated problems involving risks to subjects or others will be forwarded to the IRB for convened review. Reports of events that do not meet the requirements for prompt reporting may be returned. All other event reports will be reviewed by the expedited procedure.

7.01 Expedited Review

- a. Event reports and accompanying information will be forwarded by the ORSP's RCA (or Chair's designee) to the IRB Chair or one of the experienced members with relevant expertise as designated by the Chair for expedited review. Reviewers will have access to the complete protocol file, including previously reported events, for review. The Chair or designee will determine if the report raises new concerns about risks and will recommend further review by the convened IRB, as necessary, for a final determination. The IRB Chair may suspend or terminate approval of an investigator's research, if necessary to

assure the protection of research participants. The Chair will consider the rights and welfare of participants when suspending, terminating, or modifying research.

- b. If, during expedited review, the event is determined not to be an unanticipated problem involving risks to subjects or others, the reviewer will make any necessary recommendations for action (see below), which will be communicated to the principal investigator by the ORSP's RCA (or Chair's designee). Modifications proposed by the investigator or IRB reviewer that represent minor changes will also be reviewed by the expedited procedure. IRB members will be informed of these expedited reviews as described in the SHSU IRB's SOP #3 [Expedited Review Procedures].

7.02 Convened Review

- a. Reports of events determined during screening or expedited IRB review to represent possible unanticipated problems involving risks to subjects or others will be forwarded to the IRB for convened review. Modifications proposed by the investigator or IRB reviewer that represent more than minor changes will also be reviewed by the convened IRB. The Chair or other member with relevant expertise will serve as the primary reviewer. Copies of the reports, all other information provided by the investigator, and current consent documents (or verbal scripts) with any proposed changes will be included in the review materials for each IRB member. Sections from the protocol, previous event reports, and other relevant information or reference materials will also be included, as applicable. The complete protocol file will be available to any IRB member upon request prior to or during the convened IRB meeting.
- b. The IRB will determine by convened review whether the event is an unanticipated problem involving risks to subjects or others and if further action is necessary. Action(s) will be based on the nature of the event, degree to which research participants are placed at risk, occurrence of previous problems, etc. The IRB will consider the rights and welfare of participants when suspending, terminating, or modifying research.

7.03 IRB Actions

- a. Corrective actions (e.g., modification of the research procedures, education for investigators and/or research staff) will be considered in association with

suspensions or terminations as described in the SHSU IRB's SOP #7 [Suspensions and Termination of IRB-Approved Research]

- b. The types of actions that the IRB may consider for any event include, but are not limited to:
- (1) Modification(s) of the research protocol or procedures
 - (2) Modification(s) of the consent process or consent form
 - (3) Providing additional information to current research participants (required when such information may relate to their willingness to continue in the research)
 - (4) Providing additional information to past research participants
 - (5) Reconfirming consent of current research participants
 - (6) Requiring additional follow-up/monitoring for current and/or past research participants
 - (7) Monitoring of the research (including audits) or consent process
 - (8) Education or mentoring for the principal investigator and/or research staff
 - (9) Additional reporting, including modification of the continuing review schedule
 - (10) Requiring additional resources to support the investigator's research activities
 - (11) Placing limitations (e.g., restriction to co-investigator status) on the investigator's research activities or use of research data
 - (12) Suspending or terminating the research
 - (13) Referral to other appropriate University administrators (e.g., the Provost and Vice President for Academic Affairs, as outlined in Academic Policy Statement 920808)

- c. The IRB's determination and action(s), including votes taken, will be recorded in the meeting minutes. The requirements for quorum and majority apply. Investigators will be notified in writing by the ORSP's RCA (or Chair's designee) of IRB decisions regarding events determined not to represent unanticipated problems involving risks to subjects or others following approval of the meeting minutes by the IRB Chair. Suspended IRB approval may be reinstated, as appropriate, based on the outcome of the convened review. Investigators (and others) will be notified of IRB actions regarding events determined to be unanticipated problems involving risks to subjects or others as described below.

8. INSTITUTIONAL REPORTING

- 8.01 If the IRB determines that an event is an unanticipated problem involving risks to subjects or others, or if the Board suspends or terminates approval of research that is associated with unexpected serious harm to subjects, the investigator(s), IRB, Institutional Official, and the investigator(s)' Dean and Department Chair (or equivalent) will be notified of the reasons for the IRB's action in writing by the ORSP's RCA (or Chair's designee) within 14 days of the determination.
- 8.02 If the IRB determines that an event is an unanticipated problem involving risks to subjects or others, or if the Board suspends or terminates approval of research that is associated with unexpected serious harm to subjects, OHRP, the sponsor or any other sponsoring federal Department or Agency, and others (e.g., Office of Research and Sponsored Programs) as necessary, in accordance with The Sam Houston State University's Federalwide Assurance, will be notified in writing within 30 days. The content of the report will conform to OHRP requirements for incident reporting.

9. RECORD RETENTION

Records of reports and reviews of events representing possible unanticipated problems involving risks to subjects or others, including submission materials and communications, are retained by the Office of Responsible Research Practices for at least three years, in keeping with federal regulations, applicable state and local laws, and University policies.

10. APPLICABLE REGULATIONS/GUIDANCE

[45 CFR 46.103\(b\)\(5\)\(ii\)](#), [45 CFR 46.116\(b\)\(5\)](#), OHRP “[Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events](#)” (01/15/07), OHRP “[Guidance on Reporting Incidents to OHRP](#)” (06/20/11)

APPROVED: < signed >
Dana G. Hoyt, President

DATE: 6/17/15

CERTIFICATION STATEMENT

This academic policy statement (APS) has been approved by the reviewer(s) listed below and represents SHSU’s Division of Academic Affairs’ policy from the date of this document until superseded.

Original: April 25, 2014
Reviewer(s): Council of Academic Deans
Faculty Senate
Academic Affairs Council

Review Cycle: April 1, ENY*
Review Date: April 1, 2018

Approved: < signed >
Jaimie L. Hebert
Provost and Vice President
for Academic Affairs

Date: 6/18/15

***ENY = Even Numbered Year**