

1. GENERAL

All research involving human subjects reviewed by the convened IRB must be evaluated for issues in proposed study design and conduct that may affect the rights and welfare of human subjects, consistent with federal regulations, state and local laws, professional standards, and University policy.

2. PURPOSE

The purpose of this policy is to describe the procedures used by the convened IRB when processing and reviewing submissions for initial and continuing review and for amendments to previously approved research to ensure the protection of research participants.

3. DEFINITIONS

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

4. GENERAL INFORMATION ON CONVENED REVIEW

4.01 The IRB must provide substantive and meaningful review of research on a continuing basis, at the interval (at least once a year) established by the IRB at the prior review. IRB review must be performed by the convened IRB unless the research meets the criteria for expedited review, as described in the SHSU IRB's SOP [Expedited Review Procedures].

4.02 To be approved, research that is reviewed by the convened IRB must satisfy all of the following regulatory requirements:

- a. Risks to participants are minimized (but not necessarily eliminated) by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk. Whenever appropriate, risks to participants are minimized by using procedures already being performed for diagnostic or treatment purposes.
- b. Risks to participants are reasonable in relation to anticipated benefits (if any) and the importance of the knowledge that may reasonably be expected to result from

the research. (Note: The IRB will consider risks and benefits that may result from the research, not risks and benefits of treatments or other activities the subject would undergo even if he or she were not participating in the research.)

- c. Selection of participants is equitable, taking into account the purposes of the research and the setting in which the research will be conducted.
- d. Informed consent is sought, obtained, and appropriately documented for each prospective participant or the participant's legally authorized representative as required by the regulations.
- e. If the research involves greater than minimal risk, the data and safety monitoring plan and/or data and safety monitoring board (where appropriate) makes adequate provision for monitoring the data collected to ensure the safety of participants.
- f. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data in accordance with federal regulations (45 CFR 46.111).
- g. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, adults unable to consent for themselves, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants

5. CONVENED REVIEW PROCEDURES

- 5.01 Once application materials have been submitted and determined to be complete in accordance with the SHSU IRB's SOP [IRB Submission and Pre-Review], and once the SHUS IRB Chair determines that the IRB submission must be reviewed by the full IRB, the ORSP's Research Compliance Administrator (RCA, or Chair's designee will contact the PI(s) and then notify the Board of the assigned submission(s).
- 5.02 The ORSP's RCA (or Chair's designee) will prepare and distribute IRB materials, as described below to IRB members 3-5 days (as time permits) before convened meetings. In extenuating circumstances (e.g., IRB approval would lapse without review), when sufficient space exists on a meeting agenda for a late submission, every effort will be made to forward materials to reviewer(s) and IRB members past this deadline.

5.03 INITIAL REVIEW

- 5.03.1 All IRB members are responsible for reviewing the submitted materials in enough depth to be familiar with and prepared to discuss the information at the convened meeting. All IRB members will receive and review the following materials:
- a. Complete research protocol
 - b. Consent form(s), assent form(s) and permission form(s), and verbal script(s), including translated documents, as applicable
 - c. Recruitment materials, as applicable, including advertisements intended to be seen or heard by potential participants
 - d. Study instruments such as questionnaires, surveys, etc.
- 5.03.2 Any IRB member can access the complete IRB file for review upon request to the ORSP's RCA (or Chair's designee) prior to or during the convened meeting.
- 5.03.3 The primary reviewers are responsible for presenting findings regarding the submission and leading the discussion at convened IRB meetings. Additionally, all IRB members are responsible for the following:
- a. Declaration of any conflicting interests in accordance with federal regulations (45 CFR 46.107(e)).
 - b. Consideration of the need for any additional expertise in accordance with federal regulations (45 CFR 46.107(f)).
- 5.03.4 On behalf of the committee, the IRB Chair (and/or designee), typically, the ORSP's RCA, will communicate with the Principal Investigator (PI) following the initial review.

5.04 CONTINUING REVIEW

- 5.04.1 PIs and the IRB should “plan ahead” to meet continuing review requirements, allowing adequate time before the expiration date for review of the research

and for resolution of any modifications that may be required prior to its re-approval.

- 5.04.2 Continuing review of research is required as long as the protocol remains active and involves human subjects. This includes:
- a. Research that is open only for long-term follow-up of research participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions.
 - b. Research activities that are limited to collection or analysis of private, identifiable, or coded data
- 5.04.3 All IRB members are responsible for reviewing the submitted materials in enough depth to be familiar with and prepared to discuss the information at the convened meeting. All IRB members will receive and review the following materials:
- a. Continuing Review of Human Subjects Research application
 - b. Protocol summary (i.e., original IRB application)
 - c. Current informed consent document or any newly proposed consent documents
 - d. Recruitment materials (if still in use), including advertisements intended to be seen or heard by potential participants
 - e. Study instruments (if still in use) such as questionnaires, surveys, etc.
 - f. Any other relevant information or recent literature, especially information about risks associated with the research
- 5.04.4 In addition to the materials above, the primary reviewers are also responsible for providing an in-depth review of the following:
- a. Complete research protocol (including any amendments previously approved)

- b. Investigator's brochure, as applicable (i.e., recruitment flyer)
 - c. Questionnaires, when longer or more detailed than those normally reviewed by all IRB members
 - d. Relevant grant application or funding proposal, as applicable
 - e. All other information provided by the investigator
- 5.04.5 Any IRB member can access the complete IRB file for review upon request to the ORSP's RCA (or Chair's designee), prior to or during the convened meeting.
- 5.04.6 The primary reviewers are responsible for presenting findings regarding the submission and leading the discussion at convened IRB meetings. Additionally, all IRB members are responsible for the following:
- a. The declaration of any conflicting interests in accordance with federal regulations (45 CFR 46.107(e))
 - b. Consideration of the need for any additional expertise
- 5.04.7 On behalf of the committee, the IRB Chair and/or his or her designee, typically the ORSP's RCA (or Chair's designee), will communicate with the Principal Investigator (PI) regarding any continuing reviews.
- 5.04.8 As with initial review, the IRB must determine that the regulatory criteria for approval are met. Additionally, during continuing review, the IRB must also find the following:
- a. The informed consent document is accurate and complete
 - b. No material changes have occurred since the previous IRB review
 - c. Significant new findings that may relate to a participant's willingness to continue taking part in the research are provided
- 5.04.9 The IRB will consider obtaining verification from sources other than the investigator(s) to ensure that no material changes have occurred since previous IRB review in the following situations:

- a. Numerous protocol deviations or violations reported
- b. Inconsistent information/documentation submitted for continuing review
- c. Previous investigator noncompliance involving changes without IRB approval
- d. Complaint from research personnel or participant(s)

5.04.10 If an investigator fails to provide continuing review information to the IRB, or the IRB has not reviewed and approved a protocol by the expiration date:

- a. Research activities must stop, including recruitment, enrollment, interventions, interactions, and data analysis.
- b. For current participants, investigators, who believe it is in the best interest of individual subjects to continue participating in the research interventions or interactions, must contact the IRB Chair. The Chair will determine whether there is an overriding safety concern or ethical issue involved that justifies individual subjects' continued participation in the research.
- c. The IRB or IRB Chair will determine whether the lapse in approval should be evaluated as noncompliance in accordance with the SHSU IRB's SOP [Suspension and Termination of IRB-Approved Research].

5.05 REVIEW OF AMENDMENTS

5.05.1 Changes to IRB-approved research may not be initiated without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to participants. Minor changes to previously approved research can be reviewed by expedited procedures as described in the SHSU IRB's SOP [Expedited Review Procedures]. Changes meeting the definition of "minor changes" are described (with specific examples provided) in the SHSU IRB's SOP [Expedited Review Procedures].

5.05.2 Amendments that do not meet the criteria for expedited review must be reviewed by the convened IRB. All IRB members will be provided all modified documents (and any other information supplied by the investigator) and are responsible for reviewing the submitted materials in enough depth to

- be familiar with and prepared to discuss the information at the convened meeting.
- 5.05.3 Any IRB member can access the complete protocol file for review purposes upon request to the ORSP's RCA (or Chair's designee), prior to or during the convened IRB meeting.
- 5.05.4 The primary reviewer(s) are responsible for presenting findings regarding the submission and leading the discussion at convened IRB meetings.
- a. Additionally, all IRB members are responsible for the declaration of any conflicting interests in accordance with federal regulations (45 CFR 46.107(e)).
 - b. Consideration of the need for any additional expertise in accordance with federal regulations (45 CFR 46.107(f)) may be necessary for some of the more difficult submissions.
 - c. On behalf of the committee, the IRB Chair and/or his or her designee, typically the ORSP's RCA (or Chair's designee), will communicate with the Principal Investigator (PI) regarding any amendments.
- 5.05.5 As with initial and continuing review, for a proposed amendment, the IRB must determine that the regulatory criteria for approval are met (when the modification affects one or more criterion for approval). Additionally, the IRB must also find that significant new findings that may relate to a participant's willingness to continue taking part in the research are provided.
- a. Changes to approved research initiated without IRB approval that are made to eliminate apparent immediate hazards to subjects may represent unanticipated problems involving risks to subjects or others and should be promptly reported as described by the SHSU IRB's SOP [Event Reporting – Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems]. Such changes will be reviewed by the convened IRB to determine whether the change is consistent with ensuring the continued welfare of participants.
 - b. Completion and/or closure of a study also represents changes to research. A Final Report is submitted to notify the IRB that a study is completed or is being closed. Notification of study completion/closure may be

submitted at any time during the review period. The Final Report form should not be submitted until all research activities involving human subjects, including collection and/or analysis of private, identifiable (or coded) data, have ended.

6. IRB DETERMINATIONS AND POST-REVIEW PROCEDURES

- 6.01 The range of possible actions that the convened IRBs may take following review of research is described in the SHSU IRB's SOP [IRB Actions and Communications]. To approve research, the IRBs must determine that the research meets the regulatory criteria for approval.
- 6.02 Determination of the approval period for research approved by the convened IRBs is made as described in the SHSU IRB's SOP [IRB Actions and Communications].
- 6.03 IRB actions and findings will be reported to the principal investigator and institutional officials as described in the SHSU IRB's SOP [IRB Actions and Communications].
- 6.04 Research that has been approved by the IRBs may be subject to further review and approval (or disapproval) by officials of the institution (e.g., Institutional Official (IO), Deans, College Research Officers, etc.). However, no one may approve human subjects research (i.e., and authorize it to proceed) that has not been approved by the IRB.

7. INVESTIGATOR APPEALS/REQUEST FOR RECONSIDERATION

- 7.01 Investigators may appeal an IRB decision by submitting a request in writing, including a statement of the reason(s) for the appeal and any materials supporting the request. Supporting materials may include (but are not limited to) letters of support, current literature, and/or other information relating to the state of the art/science in the research discipline.
- 7.02 Requests for reconsideration will be reviewed by the convened IRB responsible for the determination being appealed. Decisions made by expedited review can be reconsidered by expedited review, but rejection of an appeal can be made only by the corresponding convened IRB. Investigators will be notified of and may attend the IRB meeting at which this review will occur.

- 7.03 Appeals must be made within 30 days of investigator notification of the IRB decision in question. The IRB will review the request within 30 days of receipt of the investigator’s written materials. Investigators and institutional officials will be notified of the IRB’s decision regarding the appeal within 14 days of convened review as described in the SHSU IRB’s SOP [IRB Actions and Communications].
- 7.04 The IO may not overrule IRB decisions regarding appeals in research activities involving human subjects.

8. APPLICIABLE REGULATIONS/GUIDANCE

[45 CFR 46.103](#), [45 CFR 46.111](#), [45 CFR 46.116](#), OHRP “[Guidance on Written IRB Procedures](#)” (07/01/11)

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	Review Cycle:	April 1, ENY*
Reviewer(s):	Council of Academic Deans Faculty Senate Academic Affairs Council	Review Date:	April 1, 2018

Approved:	<u> < signed > </u>	Date:	<u> 6/18/15 </u>
	Jaimie L. Hebert Provost and Vice President for Academic Affairs		

***ENY = Even Numbered Year**