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

a. Numerous protocol deviations or violations reported

b.

submitted at any time during the review period. The Final Report form should not be submitted until all research activities involving human

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

***ENY = Even Numbered Year**