1. GENERAL

The Institutional Review Board (IRB) must receive sufficient information from investigators in order to provide adequate review of proposed research and to make the determinations required by federal regulations for IRB approval.

2. PURPOSE

2.01 The purpose of this policy is to describe the submission requirements and pre-review process for research requiring IRB review.

2.02 This policy provides:

a. The steps to be taken in Institutional Review Board (IRB) submission (Initial Review, Continuing Review, changes to previously approved research [Amendment], and modifications to IRB-reviewed research), which include the Submission requirements based on IRB submission, Pre-review procedures, IRB Reviewer Assignment, and the Applicable Regulations/Guidance for these procedures;

b. A statement regarding the Collaborative Institutional Training Initiative (CITI) requirements;

c. A statement regarding the Reviewer Assignments once the IRB submission is determined to be complete by the ORSP's Research Compliance Administrator (RCA) [or Chair's designee]

3. DEFINITIONS

Go to the Glossary for definitions.

4. EDUCATION AND TRAINING (CITI REQUIREMENTS)

Individuals involved in the conduct of the research must demonstrate mastery in each area of human subjects protection addressed by the CITI training. Scores for each module must be 80% or above. This requirement applies to all individuals involved in the conduct of the research. Individuals not scoring 80% or above on each CITI module are not eligible to submit an IRB application or participate in the research process outlined by an IRB application.

5. SUBMISSION REQUIREMENTS: MATERIALS

The information listed below includes materials that are required to be submitted to the IRB for Initial Review, Continuing Review, or Amendments.

5.01 Initial Review

a. When submitting protocols for Initial Review, investigators will provide all applicable information required in the application form, which is located in SamWeb [SamWeb -> Miscellaneous -> Forms -> IRB Application].

b. In addition to the application form, PIs will submit the following information, when applicable:

(1) Consent form(s); assent form(s); parental permission form(s); Independent School District, Institution, or Agency permission form(s); and verbal script(s), including translated documents

(2) HIPAA research authorization form(s)

(3) Data collection form(s) involving protected health information in accordance with HIPAA

(4) Recruitment materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations)

(5) Script(s) or information sheet(s), including debriefing materials

(6) Instruments (e.g., questionnaires or surveys to be completed by participants)

(7) Other committee approvals/letters of support

(8) Complete grant application or funding proposal

(9) Other supporting documentation and/or materials [other than those listed above], as helpful or requested by the committee

5.02 Continuing Review

a. When submitting protocols for Continuing Review, investigators will provide all applicable information required in the application Continuing Review form.

b. In addition to the Continuing Review application form, PIs will submit the following information, when applicable:

(1) Original Initial Review IRB Application (your original submission to the IRB)

(2) Currently approved consent form(s), assent form(s), permission form(s), and verbal script(s), including translated documents

(3) HIPAA research authorization form(s)

(4) Recruitment materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) – only if still being used

(5) Script(s) or information sheet(s), including debriefing materials

(6) Instruments (e.g., questionnaires or surveys completed by participants) – only if still being used

(7) Current IRB approvals/letters of support from non-SHSU sites

(8) Complete grant application or funding proposal (new, revised, or renewals only)

(9) Other supporting documentation and/or material

5.03 Amendments

a. When submitting Amendments for IRB review, investigators will provide all applicable information required in the application form, Amendment form [Changes to Research], including one or more of the appropriate appendices.

b. In addition to the Amendment application form, PIs will submit all documentation with the proposed changes incorporated within the document(s).

c. When submitting an Amendment in conjunction with an application for Continuing Review, only the relevant appendices are required. The Amendment application is not needed in this case. In other words, there are fields provided in the SHSU Continuing Review form allowing for Amendments to the already-approved protocol to be included.

6. PRE-REVIEW PROCEDURES

6.01 Upon receipt of a submission for IRB review, ORSP's RCA (or Chair's designee) pre-reviews the materials to verify whether the application is complete as described above.

6.02 In addition, ORSP's RCA (or Chair's designee) will verify the following:

a. All individuals involved in the conduct of the research meet human subjects research education requirements (i.e., verifying the successful completion of CITI training)

b. All individuals involved in the conduct of the research meet any additional requirements (i.e., conflict of interest (COI) disclosure)

c. Review by any other committees where pre-review is required has been completed and documentation provided (i.e., Institutional Biosafety Committee review)

6.03 If an application is incomplete or modifications are required, the PI is notified by ORSP's RCA (or Chair's designee). If no response is received within 30 days, a reminder is sent, with subsequent reminders at 60 and 90 days. If no response is received within 90 days, the PI is notified that the submission will be withdrawn.

6.04 Submission materials that have been withdrawn and any related correspondence are retained by the ORSP's RCA (or Chair's designee).

Note: Submissions are not considered complete and are not forwarded for IRB review until the investigator has met all requirements for submission.

7. REVIEWER ASSIGNMENT

Once a submission is determined to be complete, the IRB Chair (or designee), typically the ORSP's RCA (1) reviews and approves all Exempt IRB applications, (2) assigns an IRB reviewer from the Board for expedited review, or (3) the submission is placed on the agenda of the next available IRB meeting as described in the IRB's SOPs [Exempt Review Procedures], [Expedited Review Procedures], or [Review of Research by the Convened IRB].

8. APPLICABLE REGULATIONS/GUIDANCE

OHRP "Guidance on Continuing Review" (11/10/10), 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**