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)

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