

1. GENERAL

- 1.01 IRB Authorization Agreements (IAA) are written agreements entered into to reduce duplicate IRB review when appropriate. Sam Houston State University (SHSU) may enter into an IAA to rely on another institution's IRB review or to allow another institution to rely on SHSU's IRB review. SHSU may enter into an IAA after a determination is made that it is appropriate under the particular circumstances. The SHSU Institutional Official (IO) retains final authority to determine whether SHSU may enter into an IAA.
- 1.02 Each IAA is situation and context-dependent. Considerations of whether to enter into an IAA may include engagement of the institutions; the location of the research interaction or intervention or subject recruitment; whether there is a prime award for a contract, grant, or cooperative agreement; whether there is a subcontract; review and approval of other university committees.
- 1.03 Before approving the ceding of human subjects review and oversight to a non-SHSU IRB, the Office Research and Sponsored Program's (ORSP) Research Compliance Administrator (RCA) or the IRB should have confidence in the capacity and compliance of the non-SHSU IRB. This may be in the form of knowledge of and respect for the other institution and its human subjects program (e.g., Texas State University, San Marcos).
- 1.04 If SHSU is asked to cede human subjects authority to a non-SHSU IRB that is unknown to us, it is appropriate to ask for a copy of that institution's human subjects protection policies and procedures; to check the Office of Human Research Protections (OHRP) website for recent compliance memoranda; to verify, through the OHRP website, that a current Federalwide Assurance (FWA) exists; and other mechanisms. If there is no information on which to base a determination of IRB competence and compliance, the IRB authorization agreement should not be approved. If the institution is found to have equivalent protections, an agreement may be entered into between SHSU and the institution.

2. PURPOSE

The purpose of this SOP is to delineate the procedures that SHSU's IRB would follow when entering into an IRB Authorization Agreement (IAA) with a non-SHSU institution (Note: these same procedures are also used when a non-SHSU institution would like to enter into an IAA with SHSU's IRB).

3. DEFINITIONS

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

4. PROCEDURE FOR ESTABLISHMENT OF THE IAA

- 4.01 An IAA is an agreement between two FWA-holding institutions to allow one of the institutions to review, approve and oversee human subjects research on behalf of the other institution.
- a. An IAA can cover all research performed by one of the institutions, or it can be specific to a particular study. Alternatively, it could cover a defined set of research projects.
 - b. When an institution cedes human subjects review and oversight authority to another federally- approved IRB (an IRB operating under a current FWA), the institution performing the research maintains accountability for compliance with all federal human subjects regulations and the IRB determinations.
 - c. If a study is operating under the approval of a SHSU IRB and the PI of that study communicates his/her preference for SHSU to cede human subjects oversight authority to another federally- approved IRB involved in the study, the ceding request must go to the IRB that approved the study. This request must be placed on the agenda of a regularly-scheduled IRB meeting. The IRB will decide, by a formal vote, whether the study will be ceded, and the IRB's decision will be documented in the meeting minutes. This decision cannot be made under an expedited review procedure.
- 4.02 The SHSU PI must provide a legitimate justification for ceding IRB oversight to a non-SHSU IRB. The non-SHSU IRB must have a legitimate role in the study; that

role cannot be as sponsor of the study or as an agent of the sponsor (e.g., a Contract Research Organization). This is a conflict of interest.

- 4.03 If the SHSU IRB agrees to cede oversight authority to a non-SHSU IRB or to accept authority ceded by another institution, the Human Studies Program must develop and facilitate the execution of an IAA between the two FWA-holding institutions. Note: The IAA must be signed by the FWA IO of both institutions.
- 4.04 If the study has not been submitted to the SHSU IRB for approval, the decision to cede authority to a non-SHSU IRB can be made by the ORSP's RCA, in consultation with the IRB Chair.
- 4.05 If an investigator from a non-SHSU IRB wishes to cede human subjects approval and oversight authority to the SHSU IRB, the ORSP's RCA, in consultation with the IRB Chair as appropriate, has the authority to make this decision. This authority should not be delegated. Typically, SHSU must have a role in conducting the study.
- 4.06 In the negotiation process, both IRBs may agree to maintain certain communication throughout the study. For example, the IRB that has accepted human subjects authority may agree to submit relevant meeting minutes, or other documents, to the IRB that has ceded authority. Such agreements should be documented in writing.
- 4.07 All communication concerning ceding authority for human subjects protection must be between the SHSU Protection of Human Subjects Committee (PHSC) and an SHSU investigator. It is not appropriate for a representative of a non-SHSU IRB to contact the SHSU PHSC directly to request a ceding arrangement.
- 4.08 A fully-executed IAA Authorization Agreement must be kept on file at both institutions and provided to OHRP upon request. The RCA maintains the files of IAAs for the SHSU PHSC. SHSU has a template IRB Authorization Agreement form. However, other forms are accepted by OHRP.

5. SHSU IRB RESPONSIBILITIES

IRB relied upon (i.e., SHSU's IRB) must agree to:

- a. Comply with that institution's FWA

- b. Follow that institution's written procedures for reporting findings to institutional officials
- c. Allow that institution to review minutes upon request
- d. Consider that institution responsible for complying with the IRB's determinations and the FWA
- e. The IAA must be available for review by OHRP upon request

APPROVED: < signed >
Dana G. Hoyt, President

DATE: 6/18/15

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: 6/23/15

***ENY = Even Numbered Year**