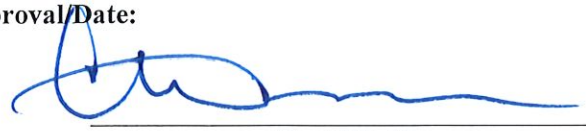
OFFICE OF RESEARCH AND SPONSORED PROGRAMS *Division of Research Compliance*		**Institutional Review Board (IRB) Standard Operating Procedures**	
Title: Collaborative Research Study Procedures			
Effective Date:	30-Apr-2014	**Document Number:**	IRB-SOP- 010.01
Approval Date:  **Chad W. Hargrave** **Vice President & Chief Research Officer**		29 OCT 2024 **Date**	

REVISION HISTORY		
28-Jul-2023		

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the IRB's oversight, to outline the responsibilities of Principal Investigators when participating in or leading multi-site research, and to describe the information that must be provided to the IRB regarding the oversight, operations, and procedures which will be used during the conduct of a multi-site research study.

SCOPE

This SOP delineates systematic process activities and functions for compliance with the US Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and SHSU requirements for the management, coordination, and operation under the oversight of the IRB. It applies to all researchers, including students and research staff involved in conducting human subjects research, as well as all IRB members and IRB staff reviewing research involving human subjects.

DEFINITIONS AND ABBREVIATIONS

1. Definitions
   - 1.1. *Lead Site:* The home site of the lead investigator for the entire project. For federally funded and/or FDA-regulated multi-site projects, the "primary awardee" or "grantee institution" will typically be designated as the coordinating or lead site. The lead site is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.
   - 1.2. *IRB Analyst:* Staff member of Research Compliance that performs administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.
   - 1.3. *IRB Authorization Agreement (IAA):* An agreement that states an institution agrees to transfer oversight of a project under its jurisdiction to another IRB. SHSU IRB requires a signed agreement to be in place prior to final IRB approval of the project. Also known as "defer," "cede," or "rely." If the IRB of Record for non-SHSU sites is the SHSU IRB, an IAA must be in place.

1.4. *IRB of Record:* The IRB responsible for review of research involving a participating site.
1.5. *Multi-Site Study:* A human subjects research project that will be initiated at more than one location other than or in addition to SHSU.
1.6. *Principal Investigator: The individual actively leading and/or supervising the initiation, execution, and completion of a research project in compliance with applicable laws, regulations, and institutional policy governing research conduct.* It is the PI's responsibility to ensure that all personnel actively working on the project and interacting with human subjects are following the guidelines of the approved protocol and are treating subjects in a manner befitting ethical use of human subjects. The PI should be the party responsible for submitting the research protocol, providing the IRB with requested changes in order to obtain approval, and for following the guidelines stipulated for annual review of the protocol and submission of any modification requests.
1.7. *Researcher:* Any individual performing various tasks related to the conduct of human subjects research activities, including but not limited to obtaining informed consent from subjects, collecting, and analyzing data, interacting with subjects, and communicating with the IRB.
1.8. *Site Authorization:* A letter from appropriate leadership within an organization/institution where research is taking place, allowing for research to take place at their organization/institution. This letter should outline the terms to which research is allowable at their site.
1.9. *SMART IRB:* standing for the Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform, it is not an IRB; rather, it is a platform that encompasses a common IRB reliance agreement and a suite of web-based resources to facilitate single IRB arrangements.

2. Abbreviations
2.1. FWA: Federal Wide Assurance
2.2. IAA: IRB Authorization Agreement
2.3. IRB: Institutional Review Board
2.4. OHRP: Office for Human Research Protections
2.5. PI: Principal Investigator
2.6. RCU: Research Compliance Unit
2.7. sIRB: Single Institutional Review Board
2.8. SOP(s): Standard Operating Procedure(s)

RESPONSIBILITIES

This SOP is applicable to all members of Research Compliance Unit (RCU) within ORSP and IRB members involved in record keeping, reviewing, or approving research studies for the IRB. This SOP is also applicable to all SHSU Researchers performing human subjects research under the oversight of the SHSU IRB.

PROCEDURE

1. SHSU IRB will not enter into a reliance agreement with institutions that do not have an IRB that is covered under an FWA, so the first step in negotiating this type of agreement is determining if the institution's IRB is covered under an FWA.
2. SHSU IRB will not enter into a reliance agreement with institutions when an exempt determination is provided for the proposed study. Instead, the PI of the proposed research

would be required to add any external researchers to their IRB submission. In turn, their collaborators would need to verify with their institution's IRB office to comply with any of their requirements regarding approval to work on the project.

3. The SHSU IRB defines its scope of oversight jurisdiction to include studies falling in the following categories:
   3.1 Human subjects research conducted at SHSU
   3.2 Human subjects research conducted by, collaborating with, or initiated by SHSU faculty, staff, or students.
   3.3 Human subjects research conducted with the use of SHSU resources, including recruitment of SHSU faculty, staff, or students.
4. All projects meeting the scope noted above must be submitted to the SHSU IRB for review and approval or site authorization.
5. All researchers listed on a SHSU IRB submission, who are not affiliated with SHSU, and are affiliated with an institution that has an IRB covered under an FWA must:
   5.1 Submit a copy of the IRB approval letter sought from their local IRB; or
   5.2 Request that the SHSU PI obtain an IAA through Research Compliance at SHSU either using SMART IRB or OHRP's IAA template form.
6. All SHSU Researchers engaged in research outside of SHSU, which has received IRB approval from an institution other an SHSU, must submit the study for review to the SHSU IRB, and secure approval.
   6.1 The external IRB approval letter, consent form, and documents must be submitted through the IRB submission portal as an initial study, reviewed, and approved by the SHSU IRB before a SHSU researcher can engage in research activities.
   6.2 The only exception is if an IAA has been sought and signed to cover activity for this project.
7. All external researchers who wish to recruit SHSU faculty, staff, or students and who have received an IRB exemption determination from their local institution must obtain site authorization from SHSU before conducting research at SHSU.
   7.1 The external IRB exemption letter, consent form, and other related documents must be submitted to the SHSU IRB for review. If appropriate, the SHSU IRB office will provide a site authorization letter.
   7.2 For exempt studies, SHSU may grant a site approval letter to the external research team, allowing them to recruit from the SHSU population.
   7.3 For expedited or full board studies, a site authorization letter may not be appropriate. Instead of a site authorization, the researcher should identify a SHSU researcher willing to serve as PI and obtain SHSU IRB approval or enter an IRB Authorization Agreement.
   7.4 Site authorizations will only be provided to external researchers if there are no SHSU researchers engaged in Human Subjects Research. If a SHSU researcher is engaged in Human Subjects Research, the SHSU researcher must obtain SHSU IRB approval.
   7.5 The external researcher must identify a SHSU research faculty member to oversee the research activities at SHSU and ensure SHSU policies and procedures are being followed.
8. SHSU IRB is willing and able to serve as both the IRB of Record (Institution A) or the relying institution (Institution B).

8.1 Both engaged institutions must agree on the site that will serve as the IRB of Record (Institution A) for the research procedures at all sites as described in the approved IRB study.

8.2 This relationship requires the institutions to enter into an Institutional Authorization Agreement (IAA).

8.3 An IAA cannot be initiated with an agency that does not have a federally approved human subjects research program, or Federalwide Assurance approval.

8.3.1 If a SHSU researcher wishes to conduct research elsewhere, such as at a privately-owned business or a secondary school which does not have an IRB, they must obtain approval from that agent to conduct research on their premises but must obtain IRB approval from the SHSU IRB.

8.4 A full research protocol must be approved by one of the institution's IRB, and the IAA states that Institution A will act as IRB of Record for the proposed project.

8.5 IAAs are executed on a study-by-study basis. An IAA must be signed for each individual study being performed by multi-site collaborators.

9. If a Principal Investigator wishes for SHSU research to rely upon a non-SHSU IRB for review and approval of a project or for a non-SHSU IRB to rely on the SHSU IRB for review and approval of a project, known as an IAA request, the Principal Investigator must submit this request to Research Compliance.

9.1 All IRB IAA requests must be initiated by emailing irb@shsu.edu

9.2 The Principal Investigator, or designee, must provide information related to the research in the format requested by the SHSU IRB staff.

9.3 All IRB IAA requests will be reviewed in the order they are received

9.4 Principal Investigators should be aware that IRB IAA requests are reviewed on a case-by-case basis and the request may be denied.

10. Relying on an External IRB:

10.1 When Research Compliance is notified of a request to rely on another IRB, an IRB Analyst will log the request, review the information, contact the PI for any additional information needed.

10.1.1 This may include the following documents:

10.1.1.1 Informed Consent/Assent forms

10.1.1.2 Protocol

10.1.1.3 Delegation of activities

10.1.1.4 IRB Approval Letter

10.1.2 Research Compliance will contact the appropriate IRB office regarding the proposed reliance request.

10.1.3 Principal Investigators should allow 2 weeks for initial intake and review.

10.1.4 If the outside IRB has agreed to provide IRB review for the project, Research Compliance will obtain the appropriate IAA form and route for signature by the Institution Official at SHSU and send it to the collaborating IRB for signature.

10.1.5 Research activities may not begin at SHSU until the external IRB grants permission to do so.

11. Relying on SHSU IRB:

11.1 When Research Compliance is notified of a request for SHSU IRB to serve as the IRB of Record for multi-site research, an IRB Analyst will log the request, review the information, contact the PI for any additional information needed.

11.1.1 This may include the following documents:

11.1.1.1 Protocol number

11.1.1.2 Informed Consent/Assent forms and any proposed changes

11.1.1.3 Delegation of activities

11.1.1.4 Research Compliance will contact the appropriate IRB office regarding the proposed reliance request.

11.1.1.5 Principal Investigators should allow 2 weeks for initial intake and review.

11.1.1.6 Principal Investigators should be aware that IRB IAA requests are reviewed on a case-by-case basis and the request may be denied based on several factors including, but not limited to, the risk of the study.

11.1.1.7 If SHSU IRB agrees to provide IRB review for the project, Research Compliance will obtain the appropriate IAA form and route for signature by the Institution Official at SHSU and send it to the collaborating IRB for signature.

11.1.1.8 Research activities may not begin at SHSU until SHSU IRB grants permission to do so.

12. SMART IRB

SHSU has signed the SMART IRB joinder agreement. When the organizations participating in the research are signatories to the joinder agreement, IRB reliance may be requested and documented utilizing the SMART IRB online reliance platform. In collaboration with the other participating organizations, SHSU will determine on a study-by-study basis whether the SMART IRB SOPs or alternative procedures will be utilized to implement the reliance. When appropriate, the SHSU IRB office will utilize the SMART IRB agreement (e.g., for a multi-site project, when required by other institutions, etc.) to ensure increased efficiencies and that consistent terms and responsibilities are followed.

13. NIH Single IRB Requirement:

13.1 All NIH multi-site studies are required to rely on a single IRB (sIRB) to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46.

13.1.1 The NIH Single IRB (sIRB) policy applies to grant applications proposing non-exempt human research which are received for due dates on or after January 25, 2018.

13.1.2 The sIRB must have the necessary infrastructure to support the required activities (e.g., administrative or regulatory staff, policies, procedures, workflows, and technology).

13.1.3 In reviewing multi-site research protocols, the sIRB may serve as a Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

13.1.4 The sIRB can delegate to relying institutions the ability to monitor or observe the conduct of the research and/or the consent process.

13.1.5 The sIRB must review and approve proposed management plans for investigators determined to have a financial conflict of interest.

13.1.6 Participating sites are responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB.

13.1.7 Participating sites must communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations. Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review.

13.1.8 Participating sites must also:

13.1.8.1 Report incidents of protocol deviations, noncompliance, or unanticipated problems to the sIRB;

13.1.8.2 Monitor the conduct of the research activities if specified in the IAA;

13.1.8.3 Ensure appropriate disclosure and management of any potential related Conflict of Interest and submit documentation to the sIRB for review

13.1.8.4 Report to the sIRB any changes to research implemented to eliminate immediate hazard or risk to participants

13.1.8.5 Ensure any local required reviews (i.e., Biosafety, Radiation Safety) are conducted in accordance with local policies and procedures prior to the implementation of research activity.

13.1.9 The policy does not prohibit any participating site from duplicating the sIRB. However, IRB ethical review at a participating site would be counter to the intent and goal of this policy.

13.1.9.1 If this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review.

13.2 The SHSU Principal Investigator should contact Research Compliance as early in the grant writing process as possible to either confirm that SHSU IRB can serve as the sIRB for the study, or to assist the Principal Investigator in making alternative arrangements.

14. Tracking Reliance Agreements

14.1 Reliance agreements will be tracked through Cayuse Human Ethics in the form of a brief Initial Submission application.

14.2 Once the SHSU IRB office receives the partially executed IRB reliance agreement, it will be posted and managed internally via a platform called Airtable.

14.3 When a reliance agreement is partially executed, the IRB office will open an agreement tracking record to begin the tracking process.

14.4 Once the fully executed agreement is received, Airtable will be updated to include the executed date, and if applicable, the expiration date.

14.5 The IRB office will receive an automated notification 3 months prior to the expiration date of the IRB associated with the reliance agreement, which will give

4. SMART IRB About Us: https://smartirb.org/about-us/
5. SMART IRB SOPs
6. UNT IRB SOPs
7. SHSU IAA—Serving as IRB of Record
8. SHSU IAA—Relying on External IRB

APPENDICES

1. IRB SOPs
2. SHSU IRB Institutional Profile