
	OFFICE OF RESEARCH AND SPONSORED PROGRAMS <i>Division of Research Compliance</i>	Institutional Review Board (IRB) Standard Operating Procedures	
	Title: Training and Education		
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PURPOSE

This Standard Operating Procedure (SOP) defines the training requirements and review considerations for all research team members, including the Principal Investigator, involved in human subjects research activities, and for Institutional Review Board (IRB) committee members and IRB office staff members administratively supporting the Human Research Protection Program (HRPP) at Sam Houston State University (SHSU).

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 of the HRPP. It applies to all staff members who are engaged in the operations and support of the IRB, and to all SHSU researchers performing human subjects research.

DEFINITIONS AND ABBREVIATIONS

1. Definitions

- 1.1. *CITI Training*: Web-based training in research ethics and compliance provided by the Collaborative Institutional Training Initiative (CITI).
- 1.2. *Co-Investigator*: Any individual member of the research team designated and supervised by the Principal Investigator to perform study-related procedures and/or make important study-related decisions (e.g., graduate or undergraduate students).
- 1.3. *External Collaborator*: Any individual proposing to conduct research using any SHSU property, facility, participant population who is not a SHSU faculty member, staff member, or student. External Collaborators must perform research activities in partnership with a SHSU Principal Investigator.
- 1.4. *Human Research Protection Program*: An institutional-wide program administered through SHSU’s Office of Research and Sponsored Programs (ORSP). It provides support and resources to the IRB and the SHSU research community. The SHSU HRPP

aims to protect the rights and welfare of research volunteers by providing support, guidance, and education to facilitate research that is ethical and scientifically sound.

- 1.5. *Human Subjects Research Activity*: Any activity that contributes to the scientific development or execution of a human subjects research study in a substantive, measurable way. This includes, but may not be limited to, activities involving recruitment, interaction, or intervention with human subjects, participation in the consent process by either leading it or contribution to it and recording or processing identifiable private information.
- 1.6. *IRB Analyst*: Staff member of the Research Compliance Unit (RCU) within the Office of Research and Sponsored Programs (ORSP) that perform administrative activities, pre-reviews, reviews, and approvals for the IRB.
- 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. *Principal Investigator*: The primary individual responsible for the preparation and conduct of a research grant, sponsored project, or human subjects research study, in compliance with applicable laws, regulations, and institutional policy governing the conduct of research.

2. Abbreviations

- 2.1. CITI: Collaborative Institutional Training Initiative
- 2.2. Co-I: Co-Investigator
- 2.3. HRPP: Human Research Protection Program
- 2.4. SOP(s): Standard Operating Procedure(s)
- 2.5. OHRP: Office for Human Research Protections
- 2.6. ORSP Office of Research and Sponsored Programs
- 2.7. RCU: Research Compliance Unit
- 2.8. IRB: Institutional Review Board
- 2.9. PI: Principal Investigator

RESPONSIBILITIES

This SOP applies to all SHSU researchers performing human subjects research under the oversight of the SHSU IRB. This SOP also applies to all members of RCU and IRB members who are involved in record keeping, reviewing, or approving research studies for the HRPP.

PROCEDURE

1. General Responsibilities for SHSU researchers, IRB members, and other individuals involved with the HRPP

- 1.1. Individuals involved in the conduct of the research must demonstrate mastery in each area of human subjects protection addressed by the CITI training program. Scores for each module must be 80% or above. Individuals not scoring 80% or above on each CITI module run the risk of their IRB submission review being delayed. As such, quizzes may be retaken as many times as necessary to achieve the required score.

- 1.2. This reflects SHSU's commitment to the protection of the rights and welfare of human subjects in research.
- 1.3. These training and scoring requirements are applicable to:
 - 1.3.1. All researchers engaged in human subjects research activity
 - 1.3.2. All RCU staff
 - 1.3.3. All IRB members
- 1.4. Training must be renewed every 5 years.
- 2. Researcher and External Collaborator Responsibilities**
 - 2.1. All members of the research team—PI's, Co-I's—including students, external collaborators, etc. must complete one or more courses in the CITI training program.
 - 2.2. External collaborators will be expected to provide their CITI training (or a similar ethics training) completion report to their SHSU collaborator for inclusion in the SHSU IRB submission (click [here](#) for a sample of what is needed).
 - 2.3. If an external collaborator can provide documentation verifying that they have successfully completed human subject research training equivalent to that required by this SOP, that individual may request a substitution of the requirements noted above. The RCU or designee will review the documentation and determine if it satisfies organizational standards as defined in this SOP. This will be assessed on a case-by-case basis. An example of acceptable alternative training is OHRP's human ethics training. Click here [for](#) more details.
 - 2.4. If an external collaborator is not required to complete ethics training at the institution with which they are affiliated, s/he will be required to complete SHSU's human research ethics training at www.citiprogram.org (click [here](#) for more details on getting started).
 - 2.4.1. SHSU researchers are required to complete one or more of the following *Human Subjects Research* courses (depending on a PI's discipline):
 - 2.4.1.1. Biomedical Researchers if PI's are engaged in clinical trial research
 - 2.4.1.2. Social-Behavioral-Educational Researchers if PI's are engaged in social, behavioral and educational research.
 - 2.4.1.3. Criminal Justice if PI's are engaged in Criminal Justice research involving prisoners.
 - 2.5. Because Cayuse supports integration with CITI Program to display training data in Cayuse Human Ethics, researchers are responsible for ensuring that their training is completed and up-to-date prior to submitting their research to the IRB. For the CITI integration to work properly, researchers are required to confirm that their correct SHSU email address is provided to the CITI training program as their **primary** email address. Because a researcher's CITI training account follows them at this and other institutions, the RCU strongly encourages all researchers to provide the CITI training program with a **secondary** email address.
 - 2.6. Evidence of training for each member of the research team will be verified during the IRB pre-review process for both initial and renewal IRB submissions. New studies and applications for renewal will not receive final approval until all education requirements have been met.

2.7. The RCU is willing to perform one-on-one or group training related to human subjects research by request. Individuals requesting training must contact the RCU staff to discuss and schedule the desired training. Researchers can click on the following [scheduling link](#) and choose a time/date that works best for them.

3. RCU Staff and IRB member responsibilities

- 3.1. All RCU staff and IRB members responsible for the review and approval of human subjects research must complete the following CITI Training courses:
 - 3.1.1. Biomedical Researchers, Social-Behavioral-Educational Researchers, Criminal Justice (RCU staff only).
 - 3.1.2. IRB Members (SHSU faculty-appointed IRB members only).
 - 3.1.3. IRB Community Members (unaffiliated IRB members only).
 - 3.1.4. The IRB Chairperson must also complete the IRB Chair course.
 - 3.1.5. The Institutional Official (also known as the Associate Provost and Chief Research Officer) must complete the Institutional/Signatory Officials course.
- 3.2. Evidence of training must be stored by the RCU for reference.
- 3.3. Training must be renewed every 5 years.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. CITI Research Ethics and Compliance Training [website](#)

APPENDICES

1. IRB Guidelines
2. SHSU [Compliance](#) website- Resources