



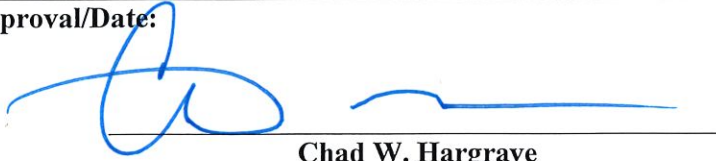
**OFFICE OF RESEARCH AND SPONSORED PROGRAMS**  
*Division of Research Compliance*

**Institutional Review Board (IRB)**  
**Standard Operating Procedures**

**Title:** Limited IRB Review Procedures

**Effective Date:** 21-Jul-2023      **Document Number:** IRB-SOP-011.01

**Approval/Date:**



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*12 Jan 2024*  
**Date**

**REVISION HISTORY**


**1. PURPOSE**

This SOP describes the procedure for conducting a Limited IRB Review, as described in the revised Common Rule (implemented January 21, 2019). All procedures are conducted by the IRB member assigned to do the review, except where noted.

**2. SCOPE**

This SOP delineates systematic process activities and functions for compliance with the U.S. 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.

**3. DEFINITIONS AND ABBREVIATIONS**

**3.1. Definitions**

- 3.1.1. *Limited IRB review (LIRB)*: a type of IRB review that is required for granting exempt status in some circumstances for exempt categories 2 and 3.
- 3.1.2. *Code of Federal Regulations*: codification of the general and permanent regulations promulgated by the executive departments and agencies of the federal government of the United States. The CFR is divided into 50 titles that represent broad areas subject to federal regulation. The regulations guiding all IRB review are found at 45 CFR 46.
- 3.1.3. *Common Rule*: also known as the Federal Policy for the Protection of Human Subjects, it is the single set of regulations that was published in 1991 and codified in separate regulations by 15 federal departments and agencies (including the United States Department of Health and Human Services (DHHS), which SHSU is subject to follow).

**3.2. Abbreviations**

- 3.2.1. CFR: Code of Federal Regulations
- 3.2.2. DHHS: Department of Health and Human Services
- 3.2.3. LIRB review: Limited IRB review
- 3.2.4. IRB: Institutional Review Board

- 3.2.5. SHSU: Sam Houston State University
- 3.2.6. SOP(s): Standard Operating Procedure(s)

#### 4. RESPONSIBILITIES

- 4.1. This SOP delineates the systematic process for conducting a Limited IRB review of a request for IRB approval.
- 4.2. The process begins when the IRB office assigns a submission to an IRB reviewer.
- 4.3. The process ends when the IRB approval has been released to the research team.

#### 5. CONTEXT

- 5.1. Similarities with expedited IRB review:
  - 5.1.1. LIRB is conducted by an IRB member authorized to conduct expedited IRB review.
  - 5.1.2. The research must be considered minimal risk.
  - 5.1.3. LIRB is focused on one standard criterion (46.111(a)(7)) for IRB approval: there are appropriate protections for privacy of subjects and confidentiality of data.
  - 5.1.4. There is no expiration date associated with approval granted through LIRB.
  - 5.1.5. Institutions can rely upon other IRBs to conduct a LIRB and thereby grant exempt status. The reliance must be documented in writing, including the responsibilities of each entity, in the standard way for any reliance. This reliance will need to be tracked through Cayuse Human Ethics in section 1 of the initial submission.
- 5.2. Differences compared with expedited IRB review.
  - 5.2.1. Because LIRB focuses on only one of the standard IRB criteria for approval, many of the waivers and determinations associated with expedited IRB review are not required.
  - 5.2.2. Granting LIRB approval to a study simultaneously grants exempt status to the study.
  - 5.2.3. After LIRB approval has been granted, the study is exempt and there are no longer any formally designated IRB responsibilities.
  - 5.2.4. The LIRB approval letter issued by Cayuse Human Ethics will indicate that the study was reviewed and approved under this review type.
- 5.3. Researcher responsibilities.
  - 5.3.1. Application process. The process and materials are the same as for any proposed human subjects research activity.
  - 5.3.2. Post-approval. The study is simultaneously granted exempt status with approval. This means:
    - 5.3.2.1. Continuing review is not required.
    - 5.3.2.2. Modification applications are required for all changes being considered by the researcher as this might affect the exempt status. Researchers are responsible for submitting a Modification application for the IRB to review. The following list describes changes that require a Modification application (**note: this is not an all-inclusive list**):
      - 5.3.2.2.1. Research personnel additions or deletions
      - 5.3.2.2.2. New types of subjects, data, or specimens
      - 5.3.2.2.3. New types of procedures
      - 5.3.2.2.4. Increased risk or assessment that risk is greater than previously realized
      - 5.3.2.2.5. Obtaining funding to conduct the research
      - 5.3.2.2.6. New survey/interview questions
      - 5.3.2.2.7. Adding or deleting a recruitment site

#### 6. PROCEDURE

- 6.1. **Identify the necessity for LIRB.** This is accomplished through the standard IRB Analyst pre-review process. At the conclusion of pre-review, an expedited reviewer is assigned to conduct the LIRB.
- 6.2. **Conduct the review.**
  - 6.2.1. **Criterion for approval.** The application materials are reviewed against the applicable criterion for approval (45 CFR 46.111(a)(7)): When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
  - 6.2.2. **Consent process and/or form.** Exempt research is not required to have a formal consent process or form. The LIRB reviewer will not review any consent process or form provided with the application. However, it is an **SHSU IRB requirement** that studies that will interact with participants are expected to provide the participants with information about the study and what will be expected of participants (see established [template](#) for exempt-eligible studies).
  - 6.2.3. **Reliance arrangements** through which the SHSU IRB is providing the review for another organization or investigator. Establish the reliance agreement, following standard procedures and submit this agreement through Cayuse Human Ethics.
  - 6.2.4. **Possible outcomes.** The Common Rule allows only the following outcomes. **The application cannot be disapproved—this can only be accomplished at a full board meeting.**
    - 6.2.4.1. Conditional approval (Revisions Required to Secure Approval (RRSA)). This is an intermediate step that must eventually result in approval or referral for standard IRB review.
    - 6.2.4.2. Approval (i.e., exempt—LIRB status).
    - 6.2.4.3. Referral for review by the expedited or convened IRB process.
    - 6.2.4.4. Determination that LIRB was not required because the activity qualifies for exempt status without LIRB or it is Not Research, Not Human Subjects, or Not Engaged.
- 6.3. **Documentation.** The outcome is documented by releasing the appropriate determination letter in Cayuse Human Ethics.
- 6.4. **Communication of outcome to the researcher.** The Exempt—Limited Review template letter is used to inform the researcher that the study is approved. The researcher will receive this communication in their SHSU email Inbox. [Here](#) is a guide for locating a pdf copy of the approval in Submission Details for their study.
- 6.5. **Report to the IRB.** The Common Rule requires all IRB members be advised of research proposals approved under LIRB or expedited procedures. This is accomplished by providing all IRB members with a report of all LIRB approvals completed outside of the convened meeting as part of IRB meeting materials.

## 7. REFERENCES

- 7.1. Revised Common Rule (45 CFR 46) references to Limited IRB Review: .103(e); .104(d)(2)(iii); .104(d)(3)(i)(c); .109(a); .109(f)(1)(ii); .110(b)(1)(iii); [.111\(a\)\(7\)](#).
- 7.2. Source of language of this SOP. Special thanks to [University of Washington IRB](#) for use of the language for our SOP.