OFFICE OF RESEARCH AND SPONSORED PROGRAMS *Division of Research Compliance*		**Institutional Review Board (IRB) Standard Operating Procedures**	
Title: Abbreviated IRB Review of Human Research Not Federally Regulated			
Effective Date:	12-Jan-2026	**Document Number:**	IRB-SOP-014.01
Approval/Date:			

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Vice President & Chief Research Officer

27 Jan 2026
Date

REVISION HISTORY		

PURPOSE

This SOP defines the criteria, process, responsibilities, documentation, and ethical standards for SHSU's Administrative/Flex (Abbreviated) Review of human research not subject to federal human subjects regulations (45 CFR 46) and not subject to FDA oversight, while upholding Belmont principles (Respect for Persons, Beneficence, and Justice).

SCOPE

This SOP applies to human research conducted by SHSU faculty, staff, students, and affiliates that is not federally funded, not FDA-regulated, does not meet the federal definition of a clinical trial, involves minimal risk, and includes appropriate privacy/confidentiality protections.

This SOP excludes research subject to the Common Rule, FDA regulations, greater than minimal risk studies, and those requiring ancillary reviews mandated by federal agreements.

DEFINITIONS AND ABBREVIATIONS

- *Administrative Level Review:* SHSU's institutional review pathway for nonregulated human research.
- *Belmont Report:* Respect for Persons (informed consent and autonomy vs. diminished autonomy), Beneficence (Risk-Benefit analysis: (1) do not harm and (2) maximize possible benefits and minimize possible harms), and Justice (equitable selection of subjects: who ought to receive benefits of research and bear its burdens?).
- *Cayuse Human Ethics:* SHSU's IRB electronic submission system.
- *FWA—Federalwide Assurance:* An assurance approved by the Office for Human Research Protections (OHRP) under which a research institution commits to comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. SHSU's FWA is limited to federally funded research.

- *Internal Equivalent Review Categories:* Exempt-Equivalent, Expedited-Equivalent, Limited-Equivalent, Full-Equivalent.
- *IRB—Institutional Review Board:* The administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Sam Houston State University.
- *IRB Abbreviated Review (aka flex review):* A streamlined IRB review process for minimal risk research that is not federally funded or federally regulated, providing equivalent protections to human participants while reducing administrative burden.
- *Limited-Equivalent review:* This review type is triggered when
    - The study is nonregulated (not federally funded, not FDA-regulated).
    - It involves identifiable information but does not pose sensitive risk (e.g., not trauma, abuse, illegal activity).
    - Requires additional privacy safeguards beyond standard minimal-risk protections.
    - Does not rise to the level of Full-Equivalent (higher risk or sensitive topics).
- *Minimal Risk:* The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests.
- *NHSR:* Not Human Subjects Research.
- *PI—Principal Investigator:* The lead researcher responsible for the conduct of the research study.
- *Protected Populations:* Groups of individuals whose ability to make voluntary, informed decisions regarding research participation may be compromised or who may be subject to coercion or undue influence. These may include, but are not limited to, children, prisoners, pregnant women, neonates, the elderly, individuals with cognitive impairments, students, and economically disadvantaged persons.
- *SHSU:* Sam Houston State University.

RESPONSIBILITIES

- Principal Investigators (PIs): Submit complete applications, complete training, protect privacy, report incidents, and comply with IRB policies and procedures.
- IRB Office: Intake screening, assign internal category, maintain records, issue determination letters, manage check-ins.
- IRB Reviewers or designee (experienced IRB Analyst): Confirm eligibility, conduct ethical review, document determinations, report outcomes.

PROCEDURE

A. IRB Office Procedure

1. Initial Screening: Determine regulated vs nonregulated vs NHSR vs 118 Determination.
2. Assign Internal Category & Cayuse Routing.
3. Insert standardized Cayuse note.
4. Issue Administrative Review Determination Letter.
5. Retain records per policy.
6. Require periodic check-ins (3–5 years depending on determination of risk to participants).

B. IRB Reviewers Procedure

1. Confirm eligibility and protections.
2. Complete reviewer checklist and internal note.
3. Approve, request modifications, or refer to convened IRB.
4. Report outcomes to convened IRB.

C. Principal Investigators (PIs) Procedure

1. Confirm eligibility and complete training.
2. Submit application in Cayuse with all required materials.
3. Submit modifications, renewals, incident reports, and closure as required.

REFERENCES

1. Newton-Wellesley Hospital. (n.d.). *Tip Sheet 27: Developing and applying equivalent protections.* https://www.nwh.org/media/file/Research%20Investigator%20Forms/Tip_Sheet_27_Guidance_on_Equivalent_Protections.pdf (Accessed 24 Oct 2025).

APPENDICES

Appendix A — Standardized Cayuse Note

ADMINISTRATIVE LEVEL REVIEW — NONREGULATED STUDY

This project is not subject to the federal human subjects regulations at 45 CFR 46. Review conducted under SHSU IRB's Admin Level Review Policy for nonregulated research. The Cayuse review category selected (Exempt, Expedited, or Full Board) is used SOLELY as an internal classification for routing and DOES NOT represent a federal IRB determination.

Internal Review Category Applied: [RESEARCH_NOTES] (**Note:** include the internal category in the Researcher Notes in the Cayuse Decision screen)

Rationale: [INTERNAL_NOTES] (**Note:** include the reason why the study meets the selected internal category in Internal Notes in the Cayuse Decision screen)

Appendix B — Administrative Review Determination Letter Template

Administrative Level Review – Nonregulated Research
Study Title: [Title]
PI: [Name]
Protocol #: [Cayuse ID]
Statement: Project not subject to 45 CFR 46 or FDA regulations. Internal category applied. Investigator responsibilities listed.

Appendix C — Internal Routing Labels in Cayuse

Internal Category	Cayuse Routing Label
Exempt-Equivalent	Exempt
Expedited-Equivalent	Expedited
Limited-Equivalent	Exempt (with note)
Full-Equivalent	Full Board