Saint Elizabeth University Institutional Review Board https://www.steu.edu/irb/

INSTITUTIONAL REVIEW BOARD (IRB) EXEMPT RESEARCH POLICY AND PROCEDURES

Compliance with 45 CFR 46 (Revised Common Rule 2018)

Institution Name: Saint Elizabeth University

IRB Policy Number: IRB-EXEMPT-001
Effective Date: 2012
Last Review Date: February 2026
Next Review Date: Spring 2028

Approved By: Dr. Patricia McQuade and Dr. Isabelle Barriere (Co-Chairs)

1. PURPOSE

This policy establishes the criteria and procedures for Institutional Review Board (IRB) determination of exempt research involving human subjects in accordance with federal regulations (45 CFR 46.104). Exempt research must present no more than minimal risk and must comply with ethical principles outlined in the Belmont Report.

2. POLICY STATEMENT

All human subjects research conducted under the authority of this institution must be reviewed by the IRB or designated reviewer to determine whether the research qualifies for exempt status. Investigators may not independently determine exempt status.

3. REGULATORY AUTHORITY

This policy complies with federal regulations governing human subjects research, including the Revised Common Rule (45 CFR 46), Office for Human Research Protections (OHRP) guidance, and institutional requirements.

4. DEFINITION OF EXEMPT RESEARCH

Exempt research refers to human subjects research activities that fall within specific federal exemption categories and present minimal risk to participants. Exempt research is exempt from continuing review but must receive an initial IRB determination.

Exempt research must first be reviewed by the SEU IRB to confirm that it meets the requirements of exemption. Although the research may be exempt from a full IRB review, the IRB must review the proposal to confirm that it qualifies and to confirm that the study design is compliant with the three leading principles of the Belmont report: beneficence, justice and the respect for persons.

Please note that RESEARCHERS ARE NOT PERMITTED TO DETERMINE ON THEIR OWN IF THEIR RESEARCH IS EXEMPT. This determination MUST be made by the IRB. Once determined by the IRB, exempt research does not require IRB approval and is then exempt from further review. Faculty members overseeing exempt research will submit documentation that they have reviewed the application and endorse the application as exempt.

5. EXEMPT RESEARCH CATEGORIES

The IRB may determine research to be exempt if it falls within one or more categories defined in 45 CFR 46.104, including educational practices, surveys, interviews, benign behavioral interventions, secondary research using existing data, public benefit research, and food quality evaluation studies.

In order to ensure that your study qualifies as EXEMPT research, please review the Federal IRB regulations at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr46/index.html#46.101

What kind of research qualifies as EXEMPT?

There are 6 categories of Exempt research. These categories are described by federal regulations from the Department of Health and Human Services. If a research proposal meets one or more of the following categories, it may be exempt from IRB review:

1. Educational Settings, Practices Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
    a. research on regular and special education instructional strategies,
    b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Educational Tests, Surveys, Interviews, Observations Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Educational Tests, Surveys, Interviews, Observations of Public Officials Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
    - the human subjects are elected or appointed public officials or candidates for public office; or
    - federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Existing Data, Documents, Records, Specimens Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Public Benefit or Service Programs Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
    - public benefit or service programs;
    - procedures for obtaining benefits or services under those programs;
    - possible changes in or alternatives to those programs or procedures; or
    - or possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and Food Quality and Consumer Acceptance Taste and food quality evaluation and consumer acceptance studies,

- if wholesome foods without additives are consumed or
- if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6. LIMITED IRB REVIEW

Certain exempt research categories require limited IRB review to ensure adequate provisions for protecting participant privacy and maintaining confidentiality of identifiable data.

7. RESEARCH NOT ELIGIBLE FOR EXEMPTION

Research involving prisoners, FDA-regulated products, greater than minimal risk, or protected populations beyond allowable exemption categories may not qualify for exemption.

8. INVESTIGATOR RESPONSIBILITIES

Investigators must submit required documentation to the SEU IRB, protect participant privacy, obtain consent when appropriate, and comply with all institutional and federal requirements. Research may not begin until IRB determination is received.

EXEMPT Research Application Process at Saint Elizabeth University. How do I submit an application for EXEMPT research to the SEU IRB?

The SEU IRB process for reviewing Exempt studies.

1. The researcher submits an email request (irb@steu.edu) to the IRB for the review and registration of an exempt study. Include this information in the email subject line.
2. In the request, the following information must be included:
    i. Name of researcher(s)
    ii. Name of research advisor (if applicable)
    iii. Academic program enrolled (if applicable)
    iv. Timeline for research. * Any research not completed within one year must have an update submitted to the SEU IRB for continuance, and at the completion of the study.
    v. Title of the research
    vi. a brief explanation of the rational for the exemption based on the categories in the federal regulations.
    vii. With the email request, include an abridged proposal submission form, so that the IRB has enough information to confirm that the study is exempt.
3. The following sections of the SEU IRB Submission Form should be completed: Items 1 -11 and Item 14.

4. For all other sections the researcher must type in "Not Applicable - Exempt Research."
5. The SEU IRB Submission Form should clearly provide evidence of the study's exempt status based on the federal regulations and must include an endorsement by the course instructor supporting the recommendation for exempt research and documenting oversight of the research project. The overseeing instructor should be included in any email correspondence with the IRB.

9. IRB RESPONSIBILITIES

The IRB or designated reviewer will evaluate submitted materials, determine exemption eligibility, document determinations, and ensure compliance with federal regulations and ethical standards.

10. DOCUMENTATION AND RECORD RETENTION

The IRB will maintain documentation of exempt determinations. Investigators must maintain research records in accordance with institutional and regulatory requirements.

11. ETHICAL PRINCIPLES

All exempt research must comply with the Belmont Report ethical principles of Respect for Persons, Beneficence, and Justice.

12. APPROVAL SIGNATURES

IRB Co-Chair Signature: Dr. Patricia McQuade Date: 2/20/26

IRB Co-Chair Signature: Dr. Isabelle Barriere Date: 2/20/26

REFERENCES:

United States Department of Health and Human Services, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr46/index.html#46.101