

## EXEMPT Research Application Process at the College of Saint Elizabeth

### What does EXEMPT mean?

Exempt research must first be reviewed by the CSE 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 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.

### 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:

- research on regular and special education instructional strategies,
- 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:

- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- 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

## EXEMPT Research Application Process at the College of Saint Elizabeth

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.

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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-cfr-46/index.html#46.101>

### Is there any research that NEVER qualifies as EXEMPT?

**YES!**

Certain kinds of research with human subjects are **NOT** eligible for exemption. This research mostly involves protected populations, like prisoners and children.

**Prisoners:** Research involving prisoners is **NOT** eligible for exemption. "Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing." (U.S. Department of Health and Human Services, <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101> )

**FDA-regulated Research:** Exempt research categories do *not* apply to research that involves FDA-regulated products.

**VA Studies:** For AVAMC Research or other VA-supported research that is not otherwise subject to FDA Regulations, only the categories of research set forth in the [VHA Handbook](#) may be classified as exempt research.

**Minors (Children):** Research involving minor may not be exempted, with one exception. If the research consists solely of observation of public behavior where the investigator does not participate in the activities being observed, the research may be eligible for exemption. All other research involving minors is not eligible for exemption.

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### How do I submit an application for EXEMPT research to the CSE IRB?

The CSE IRB piloted a process for reviewing Exempt studies in Spring and Fall of 2018. This process is a simplification of the current IRB submission process.

1. The researcher submits an email request to the IRB for the review and registration of an exempt study. In the request, the following information must be included:
  - Name of researcher(s)
  - Name of research advisor (if applicable)
  - Academic program enrolled (if applicable)
  - Title of the research
  - a brief explanation of the rationale for the exemption based on the categories in the federal regulations.
2. With the email request, include an abridged proposal submission form, so that the IRB has enough information to confirm that the study is exempt. The following sections of the CSE IRB Submission Form should be completed: 1 through 11, 14. For all other sections the researcher can leave the space blank or type in "Not Applicable - Exempt Research." The IRB Submission Form should clearly provide evidence of the study's exempt status based on the federal regulations.

### **REFERENCES:**

Emory University Institutional Review Board,  
<http://www.irb.emory.edu/policies/review-types/exempt.html>

United States Department of Health and Human Services,  
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101>

University of California – Davis, Office of Research,  
<https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/review-by-the-irb/>