

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 114	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 7/2009; 8/2011; 11/2013
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1. PURPOSE

This policy describes the process for determining whether a research proposal is eligible for exempt status and the process for approval. Federal guidelines identify those research activities that are exempt from 45 CFR 46 and therefore do not require full IRB review. If the proposed research appears to fall under one of the exempt categories described below, the Principal Investigator shall submit the protocol to the IRB Chair/Vice Chair for official determination of exempt status.

2. EXEMPT CATEGORIES FROM 45 CFR 46.101(B) AND 21 CFR PART 56.104

- 2.1. The following information on exempt categories is from [45 CFR 46.101\(b\)](#) and [21 CFR Part 56.104](#).
- 2.2. Unless otherwise required by a federal department or agency head, exempt research activities shall include those in which the only involvement of human subjects (excluding prisoners, fetuses, pregnant women, or human *in vitro* fertilization) will be in one or more of the following categories:
 - 2.2.1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
 - 2.2.2. 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 (**Note:** [identifiers as defined by the HIPAA regulations will apply to all types of research data collection](#)); 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. **NOTE:** This exemption SHALL NOT apply to children, except for research involving public behavior when the investigators do not participate in and/or influence the activities being observed.

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2.2.3. 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 2.2.2 above, if:

2.2.3.1. the human subjects are elected or appointed public officials or candidates for public office; or

2.2.3.2. federal statute(s) require without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.

2.2.4. 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.

2.2.5. Research and demonstration projects that are conducted by, or subject to, the approval of a federal department or agency head, and that are designed to study, evaluate or otherwise examine:

2.2.5.1. Public benefit or service programs;

2.2.5.2. Procedures for obtaining benefits or services under those programs;

2.2.5.3. Possible changes in or alternatives to those programs or procedures; or

2.2.5.4. Possible changes in methods or levels of payment for benefits or services under those programs.

2.2.6. Taste and food quality evaluation and consumer acceptance studies, if:

2.2.6.1. wholesome foods without additives are consumed; or

2.2.6.2. 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

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contaminant at or below the level found to be safe by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

3. SUBMISSION REQUIREMENTS

If the project qualifies for exempt status, the Principal Investigator shall submit an original of the following to the IRB:

- 3.1. [Application for Determination of Exempt Status](#);
- 3.2. Protocol or study design, including list of references;
- 3.3. Questionnaires/surveys;
- 3.4. Interview questions;
- 3.5. HIPAA authorization or [Application for Waiver of HIPAA Privacy Authorization](#) if Protected Health Information (PHI) is being collected as part of the study;
- 3.6. Advertising materials, if any;
- 3.7. Any other documents that will be given to research subjects;
- 3.8. If the research project being submitted has been previously reviewed by a local IRB other than the Creighton IRB, a copy of the approval or disapproval letter from that IRB; and
- 3.9. A copy of any other documents and/or items (e.g., description of items to be given to subject, such as diary cards, small gifts, etc.).

4. REVIEW PROCESS

- 4.1. The IRB Chair/Vice Chair shall review preliminary determinations of exempt status and shall make the final institutional determination about whether a research protocol qualifies for exemption from coverage under 45 CFR 46.101 or 21 CFR 56.104. After

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the application has been submitted, the IRB Chair/Vice Chair shall review the submission and shall notify the Principal Investigator in writing of the official determination within approximately five working days. If the Chair/Vice Chair determines that the project does not qualify for exempt status, the Principal Investigator shall be asked to submit the protocol for either expedited or full board review, as appropriate.

- 4.2. The IRB administrative staff can be contacted with any questions regarding the exempt categories defined above.

5. MODIFICATIONS TO PREVIOUSLY APPROVED PROJECTS

5.1. Submission Requirements

5.1.1. The Principal Investigator shall submit the following:

- 5.1.1.1. A letter that summarizes the changes
- 5.1.1.2. Protocol revisions with changes highlighted (track changes document)
- 5.1.1.3. Any new items or documents added to the protocol as part of the change

5.2. Review Process

5.2.1. The IRB shall review modifications to the extent that the changes do not alter the exempt status.

6. CONTINUING REVIEW OF ONGOING PROJECTS

6.1. If a project is determined to be exempt, the project shall be given a three-year approval period to conduct the study. If the Principal Investigator wishes to continue the project beyond the initial three years, the Principal Investigator shall submit the completed [“Reporting Form for Continuing Review or Project Termination for Projects Determined to be Exempt.”](#)

6.2. Submission Requirements

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6.2.1. The Principal Investigator is ultimately responsible for timely submission of continuing review materials. The IRB shall send a courtesy reminder to the Principal Investigator listed on the project prior to the expiration date of the current approval period. Continuing review materials should be submitted at least one week prior to the expiration date. The Principal Investigator shall submit the completed continuing review application.

6.2.2. Failure to complete and submit the continuing review form in a timely manner shall result in the research project being closed. If this occurs, the Principal Investigator shall be required to submit a new [“Application for Determination of Exempt Status”](#) and receive IRB approval before continuing the research. Any data collected during an expiration period shall not be used for research purposes.

6.3. Review Process

6.3.1. The IRB uses the same criteria for continuing review as it does for initial review.

7. TERMINATION OF ONGOING PROJECTS

7.1. Submission Requirements

7.1.1. The Principal Investigator is encouraged to complete the [termination application](#) (same application for continuing review). If a Principal Investigator fails to submit a termination application, the project shall be terminated three years after the initial approval or last approval of renewal (the latest date) of the project.

7.2. Review Process

7.2.1. The IRB shall update the database, review final reports, and terminate the study. After a project is terminated, there shall be no further data collected or subjects contacted.