

1. OBJECTIVE

Research activities in which the only involvement of human subjects will be in one or more specific categories, which are listed in section 1.1 of these Procedures, may be exempt from Federal review. Exempt status proposals are reviewed by the IRB Administrator. Determination of exemption must be based on regulatory and institutional criteria.

Specific Procedures

Human subjects research activities must be reviewed to determine whether the research meets one or more of the exemption categories described below and whether the research complies with applicable ethical standards. Federally-funded research determined to be exempt is not subject to 45 CFR 46 unless otherwise specified.

Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must submit an application to the BYU IRB office for final determination of exemption.

Research qualifies as exempt only if it falls into one or more of the exempt categories described below and meets these additional requirements:

- The research must present no more than minimal risk to subjects.
- The research is consistent with the ethical principles reflected in the Belmont Report, which include:
 - Respect for Persons (Autonomy). Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
 - Beneficence. Individuals should not be harmed and the research should maximize possible benefits and minimize possible harms.
 - Justice. Selection of participants should be equitable and the benefits and risks of research should be distributed fairly.
- As appropriate, there are adequate provisions to maintain the privacy interests of participants and the confidentiality of data.

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1.1 Exempt Research Activities

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review:

A. Category 1

45 CFR 46.101 (b)(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.

B. Category 2

45 CFR 46.101 (b)(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

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

C. Category 3

45 CFR 46.101 (b)(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 Category 2, if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
- (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

D. Category 4

45 CFR 46.101 (b)(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

E. Category 5

45 CFR 46.101 (b)(5) 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:

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- (i) Public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs.

F. Category 6

45 CFR 46.101 (b)(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.

Research involving prisoners

The exemption categories listed above do not apply to research involving prisoners.

Research involving children

Exemption Category 2, 45 CFR 46.101(b)(2), does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Research subject to FDA regulations

The IRB will not consider any research exempt that involves a test article regulated by the FDA, unless the research meets the criteria for exemption described in 45 CFR 46.101(b)(6) and 21 CFR 56.104(d).

Research subject to HIPAA regulations

A determination that a study is exempt does not remove relevant HIPAA considerations. If HIPAA applies to an exempt study, authorization or a waiver of authorization must be obtained.

Continuing Review

Studies confirmed as meeting the criteria for exemption are not subject to continuing review. BYU, nonetheless, remains responsible for exercising proper oversight for research conducted under its auspices. To exercise this oversight, the IRB office will annually send a notice to all PIs to confirm:

- That the research is on-going. If it is not, the PI will be asked to close out the study.
- That the PI is aware of her/his responsibilities under the BYU IRB exemption determination.

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2. SCOPE

These policies and procedures apply to Investigator claims for exemption from Federal review.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101

21 CFR 56. 104, 105

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.