



Policy Title	Exempt Research
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Responsible Office	IRB Office
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1. Policy Purpose Statement

The purpose of this policy is to provide: (1) information to investigators about what human research activities are considered exempt; (2) a description of the responsibilities of the investigators in the ethical conduct of human participant research; (3) a description of the submission and determination process for exempt research, and (4) examples of modifications to exempt research that require and do not require IRB review.

2. Definitions

Benign behavioral interventions: interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing.

Exempt Research: research that is exempt from the laws, regulations, codes, or institutional guidance that govern the research.

Federally Funded: projects with any funding or support from a US federal agency, including subawards or contracts, and projects where any research team member is compensated or supported by a federal award or contract. Also: Supported or Funded by a Federal Department or Agency.

Individually Identifiable: the identity of the participant is or may readily be ascertained by the investigator or associated with the information. Audio-recordings, video-recordings, or photographs of participants would be considered identifiable information.

Limited IRB Review: a process that is required only for certain exemptions and does not require an IRB to consider all of the IRB approval criteria in §46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.

Prospective Agreement: (a) the process of describing a benign behavioral intervention and data collection procedures prior to beginning the activities to obtain a potential participant's agreement to take part in the activities; or (b) the process of obtaining authorization from a potential participant to participate in research in circumstances in which they are informed that deception or incomplete disclosure regarding the nature or purposes of the research will be involved.

3. Policy

All research activities involving human subjects must receive IRB review prior to initiation, including human research activities that may qualify for exempt determination. Requests for IRB review are submitted through Cayuse. KSU IRB Office staff are responsible for making exempt determinations.

- 3.1. For a study to qualify for an exempt determination, the research must pose no more than minimal risk to participants, and all research activities involved must be eligible for at least one of the exempt categories. If any of the research activities is not eligible for an exempt category, then the study will be reviewed by the IRB through an expedited or full board review. Exempt Categories are listed in Appendix A.
- 3.2. When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by a designated member of the IRB and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities.
- 3.3. Research using deception or incomplete disclosure regarding the nature or purposes of the research is eligible for exempt determination if it meets the criteria for exempt determination as described in this policy and the participant authorizes the deception through a prospective agreement.
- 3.4. Restrictions on the involvement of vulnerable populations in exempt research:
 - 3.4.1. Research involving prisoners cannot be classified as exempt, except for research aimed at involving a broader participant population that only incidentally includes prisoners.
 - 3.4.2. Research involving children cannot be classified as exempt under category (2)(i) or 2(ii) if the research involves: Survey, Interview procedures, Observations of public behavior when the investigator participates in the activities being observed.
 - 3.4.3. Research involving children cannot be classified as exempt under category (2)(iii) or category (3).
- 3.5. Other state and federal regulations, laws, codes, and guidance remain applicable regardless of DHHS exempt determination. Applicable federal laws may include the Family Educational Rights and Privacy Act (FERPA) and Human Insurance Portability and Accountability Act (HIPAA).
- 3.6. Exempt research must meet the same institutional ethical standards as non-exempt research, including adequate provisions when warranted, to: protect vulnerable participants and maintain the confidentiality of the data and the privacy interests of the participants.
- 3.7. For collaborative research, an IRB Authorization Agreement, or other form of reliance agreement, will not automatically be required if the research is determined exempt by all institutions considered engaged in the collaborative research.
- 3.8. As with non-exempt research, investigators must promptly notify the IRB of any unanticipated problems involving risks to human subjects or others, including adverse events that should be considered unanticipated problems.

- 3.9. Performance of research outside of the United States does not exclude the research from consideration for exemption. However, there may be other factors, specific to the locale that would disqualify the research from exemption.
- 3.10. Except as described below, investigators are not required to submit changes to the IRB office once a research study receives an exempt determination as long as those changes do not affect the exempt category or criteria for exempt determination (changing from exempt status to expedited or full review, changing exempt category) or that may substantially change the focus of the research study such as a change in hypothesis or study design. If new external funding is obtained for an active human research project that had been determined exempt, a new exempt application will be required.
- Examples of changes in procedures that may change the exempt designation include but are not limited to:
- 3.10.1. New knowledge that increases the risk level
 - 3.10.2. Use of any methods described in the expedited review categories that do not meet the exempt criteria in the designated category.
 - 3.10.3. For projects designated under Revised Common Rule exempt category (1)(2018 Requirements): Change in which the research would likely adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
 - 3.10.4. For projects designated under Pre-2018 Common Rule exempt category (2) or Revised Common Rule exempt category (2)(i) or (2)(ii)(2018 Requirements): Addition or change to an educational test, survey procedure, interview procedure, in which any disclosure of the participant 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
 - 3.10.5. Adding a survey or interview of children or observation of public behavior of children and participating in the activities being observed.
- 3.11. Changes to exempt research in category (2)(iii) or 3(iii) that are related to the provisions to protect the privacy of subjects and to maintain the confidentiality of data, or that may impact those provisions, must be submitted as a Modification for IRB review and approval before initiation of the changes.
- Examples of changes in procedures that may impact the privacy of subjects or confidentiality of data include but are not limited to:
- 3.13.1 Change in how or where data is stored (e.g., server, cloud)
 - 3.13.2 Change in how the data is coded, or who has access to the code.
 - 3.13.3 Change in location of where the research is conducted (e.g., private location, public setting)
 - 3.13.4 Change to risk type (criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation) that may alter privacy and/or confidentiality considerations.
 - 3.13.5 Change to subject population that may alter privacy and/or confidentiality considerations.
 - 3.13.6 Change to add audio or video recording.

- 3.12. Changes related to study personnel must be submitted as a Modification for IRB review and approval before initiation of the changes.
- 3.13. Investigators must notify the IRB when the study is complete by submitting a closure request.

Appendix A

Revised Common Rule (2018 Requirements) Exempt Categories

The following exempt categories apply to research subject to the Revised Common Rule (2018 Requirements).

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the

subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects

include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
- (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.” 45 CFR 46.104(d)(2018 Requirements)

U.S. Food and Drug Administration (FDA) Exempt Categories

The following exempt categories apply to research subject to FDA regulations (i.e., clinical investigations).

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations 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.

Pre-Common Rule Exempt Categories

The following exempt categories apply to research subject to pre-2018 Common Rule regulations.

(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) 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.

(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 (b)(2) of this section, 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.

(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.

(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: (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.

(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.” 45 CFR 46.101(b)(Pre-2018 Requirements)