HUMAN RESEARCH PROTECTION

Criteria for exemption from IRB oversight

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Resource type GUIDANCE

This document may be used by researchers to consider exempt human research categories and criteria prior to IRB submissions.

The IRB, not the researcher, is responsible for determining whether research qualifies for an exemption. The Human Research Protection Office (HRPO) staff assess eligibility for exemption as part of the IRB pre-review process. (Research that is not eligible for exemption must receive either expedited or convened IRB review.)

All requests for exemption from IRB oversight must be submitted via the online IRB submission system, Cayuse HE.

Visit the HRPO website for additional information: https://www.hhrinstitute.org/researcher-resources/ohsr/

A. Basic eligibility criteria

Does the research ***intend*** to enroll PRISONERS as research participants?
If YES, the proposed research is not eligible for exemption

Will data from this research be submitted to the US Food and Drug Administration (FDA) or will researchers hold data from this research for inspection by the FDA?
If YES, the proposed research is not eligible for exemption

Does this research involve children?
If YES, DoD-sponsored research does not eligible for exemption

B. Exempt categories 45 CFR 46.104

Exempt category 1 - Educational research

Research conducted in established or commonly accepted educational settings, specifically involving 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, such as:

- Research on regular and special educational instructional strategies, or
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

NOTE: If the research involves access to student education records under the Family Educational Rights and Privacy Act, these additional regulations must also be considered.

Exempt category 2 - Anonymous/non-sensitive surveys, interviews

Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) **if at least 1 of the following criteria is met:**

i. *Information obtained is recorded by the investigator in such a manner that identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

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, or reputation.

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 the IRB will conduct a **limited IRB review** to make the determination required by §46.111(a)(7). If the study involves subjects who are children, exemption is unallowable for this criteria.

*Investigator(s) may not participate in the educational tests or observed public behavior if the study involves subjects who are children.

Exempt category 3 - Benign behavioral interventions

(unallowable if the study involves subjects who are children)

Research involving benign behavioral interventions 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:

i. Information obtained is recorded by investigator so the identity of the human subjects **cannot readily be ascertained**, directly or through identifiers;

- 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
- Information is recorded by investigator so 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).

NOTE: 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. Examples would include having the subjects play an online game, solve puzzles under various noise conditions, or deciding how to allocate a small amount of received cash between themselves and someone else.

Does the research involve deception regarding the nature or purposes of the research?
If YES, 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.

Exempt category 4 -Secondary research on existing data or specimens

Secondary research for which consent is not required: Data do not need to be existing ("on the shelf") at the time of the research study.

Secondary research uses of identifiable private information or identifiable biospecimens, if **at least one of the following** criteria is met:

(i) Identifiable private information or identifiable biospecimens are publicly available;
Publicly available refers to data and/or specimens that are accessible to anyone in the general public, without the need for special permissions or privileges. In these cases, the subjects do not have a reasonable expectation of privacy of their data/specimens.

(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;

Example: Private data, which may or may not contain identifiers, but are not clinical data subject to HIPAA regulations. Study team members **may access** identifiable private information, but **cannot record**/obtain data in a way in which it could be linked back to identifiers, even temporarily. Any individuals accessing the identifiable data must already have access to that information (by means of their involvement with the original collection). Data may not be linked to the identity of the subjects at any time.

(iii) 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, (HIPAA) 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);

Example: Direct access to medical records by Hennepin Healthcare researchers with an approved waiver of HIPAA authorization; identifiable data may be recorded when the request for a waiver of HIPAA authorization is sufficiently justified.

(iv) Research conducted by or on behalf of the federal government using information generated or collected by the government for non-research purposes, when the information is subject to other regulatory protections for data confidentiality (e.g., FISMA).

Exempt category 5 - Research conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected data obtained for non-research activities

Examples: 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
- 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. 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.

URL for this category determination must be provided in the IRB submission

Exempt category 6 - 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.

Exempt category 7 – Storage or maintenance for secondary research for which broad consent is required

NOT ADOPTED by HHRI

Exempt category 8 – Secondary research for which broad consent is required

NOT ADOPTED by HHRI