

Types of Review: Exempt, Expedited, Full Board Review

Exempt review:

Under federal regulations, certain types of research may be exempt from further IRB review if the study involves no more than “minimal risk” and falls into one or more of eight categories as outlined below. Once submitted, allow approximately 1-2 weeks for review. Either (a) determination of exemption, (b) request for revisions, or (c) notification that the project does not qualify for exemption, will sent via IRBNet e-mail notification. If the research project does not qualify for exemption, the project may be designated as non-human subjects research or may be processed as expedited review.

NOTE: Subject consent is always needed, however, signed consent is not required. The use of an Information Sheet is required and located in IRBNet forms/templates.

Once you have determined that you are doing human subject research, you should consider whether your research might qualify for as Exempt research. If you believe your research qualifies as exempt, you must complete the appropriate IRB application. (i.e., IRB Exempt Application, Retrospective Medical Records Review, or Request for Use / Storage of Biological Specimens)

Exempt categories

The Code of Federal Regulations (45 CFR 46.101 b) have developed new exempt categories, effective January 21, 2019. The biggest changes to affect non-biomedical research and include the following new categories:

1. Benign behavioral interventions (Category 3)
2. Storage or maintenance for secondary research for which broad consent is required (Category 7) (USA IRB will not implement)
3. Secondary research for which broad consent is required (Category 8) (USA IRB will not implement)

Additionally, secondary data (Category 4) **does not** have to be restricted to retrospectively collected data. Data collected in an ongoing manner are included.

Research may be classified and reviewed by the IRB as exempt if it meets one of the following definitions:

Category 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.

Category 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.

Category 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

Category 3(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.

Category 3(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.

Category 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, for the purposes of "health care operations" or "research", or for "public health activities and purposes"; 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,

Category 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, 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.

Category 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.

Category 7 (the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required) and **Category 8** (Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for which broad consent was required) **will not** be implemented at this time.

Expedited review:

The IRB may use an expedited review procedure when the research involves no more than “minimal risk” to the subjects and where the only involvement of human subjects will be in one or more of the [expedited categories](#). For example: blood draws; non-invasive specimen samples; data collected from running on a treadmill; sensitive identified interviews; and secondary data analysis from non-public sources.

Dependent on the type of research (i.e., biomedical research vs non-biomedical research), the project will be routed through the appropriate IRB committee for review and approval. See [USA IRB Committees](#) for detailed information and [IRB review chart](#).

Either (a) determination of expedited approval, (b) request for revisions, or (c) notification that the project does not qualify for expedited review, will be sent via IRBNet e-mail notification. If the protocol does not qualify for expedited status it will be processed for either exempt or full board review.

Full Board review:

All studies involving greater than minimal risk must be reviewed by a convened meeting of the IRB. Investigators planning to submit a research project for full board review should review [USA IRB Committees](#) for additional information. After review at a convened meeting either (a) determination of approval, (b) request for revisions, or (c) notification of disapproval will be issued via IRBNet email notification.