

Levels of Human Subjects Research Review

IRB must review all projects that meet the definition of research and that involve human participants prior to any data collection to determine the appropriate level of review, and, as appropriate, approve them. There are three major levels of human subjects' research review: Exempt, Expedited, and Full.

Exempt Review

Studies that receive an exemption determination from IRB are exempt from the specific regulations and requirements in Title 45, Part 46 of the Code of Federal Regulations. Please note, however, that they are still considered human subject research.

If the proposed research involves no greater than minimal risk to participants and involves any of the following, it may qualify for exempt status in accordance with the revised Common Rule (effective January 21, 2019):

- **Exemption 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.
- **Exemption 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:
 - 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.
 - 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
 - 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 that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- **Exemption Category #3.** 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:

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- 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.
- 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
- 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 that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- **Exemption Category #4.** Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available.
- 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;

The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA as "health care operations," "research" or "public health"; or

- The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities and the information is subject to federal privacy standards and other requirements specified in the exemption [Refer to 45 CFR 46.104(d)(4) of the revised Common Rule]

- **Exemption 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 (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.

- **Exemption 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

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Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- **Exemption Category #7.** Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials. [Refer to 45 CFR 46.104(d)(7), 46.111(a)(8), and 46.116(d) of the revised Common Rule.]
- **Exemption Category #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:
 - Broad consent is obtained from the subjects for the secondary research use of their identifiable materials,
 - Documentation or waiver of documentation of informed consent is obtained,
 - An IRB conducts a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and;

The investigator does not include returning individual research results to subjects as part of the study plan. [Refer to sections 45 CFR 46.104(d)(8), 111(a)(7) and 46.116(d) of the revised Common Rule]

Expedited Review

Studies that involve no more than minimal risk, but which do not meet any of the above criteria for exempt status may be eligible for Expedited Review. According to the CFR, “*minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

If the proposed research presents no more than minimal risk, does not involve any vulnerable populations (i.e., children, prisoners, individuals with impaired decisionmaking capacity, and/or economically or educationally disadvantaged persons), and involves any of the following, it may qualify for Expedited Review.

- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as for medical treatment or diagnosis).
- Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving X-rays or microwaves.
- Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) research on medical devices for which (i) an investigational device exemption application (21CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Collection of blood samples by finger stick, heel stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.
- Prospective collection of biological specimens for research purposes by noninvasive means.

Full Review

If the proposed research does not qualify for Exempt or Expedited Review as defined above, it will be subject to a Full Review. In addition, if the proposed research involves any of the following, it will be subject to Full Review.

- Children under the age of 18
- Prisoners
- Individuals with impaired decision-making capacity • Economically or educationally disadvantaged persons • Procedures that might cause physical harm.
- Procedures that might cause significant psychological/emotional distress.
- Collection of information about highly sensitive topics.
- Collection of information about illegal behavior.
- Collection of information that could seriously harm the participant legally, socially, financially etc. if other people could identify them.