John Carroll University | Institutional Review Board

Exempt Research Categories

The federal government requires that ALL research proposals involving human subjects be on file with the IRB. It exempts, however, certain types of research from the requirements of 45CFR46 and therefore from formal IRB review. John Carroll University IRB Policy requires that the research protocols for all exempt research undergo a limited review by the IRB Office before an Exemption Notice can be issued. (The four most common research categories are in bold)

Exempt Categories from 45 CFR 46.104 (d)

Exempt 1: Educational Research

Exempt 2: Minimal-Risk Tests, Surveys, Interviews, or Observations

Exempt 3: Benign Behavioral Interventions

Exempt 4: Secondary Research of Identifiable Private Information or Biospecimens

Exempt 5: Federally Supported Research for Public Benefit or Service Programs

Exempt 6: Taste and Food Quality Evaluations

Exempt 7: Creation of Data/Biospecimens Repositories for which Broad Consent is Required

Exempt 8: Secondary Research using Data Repositories for which Broad Consent is Required

Exempt 1: Educational Research

(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.

Exempt 2: Minimal-Risk Tests, Surveys, Interviews, or Observations

(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) DE-IDENTIFIED: 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; OR

(ii) NOT RISKY: 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) IDENTIFIABLE and WITH LIMITED IRB REVIEW: 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).

NOTE: Exempt 2 does not apply to research with CHILDREN except for research involving observations of public behavior when the investigators do not participate (interact/intervene) in the activities being observed.

Exempt 3: Benign Behavioral Interventions

(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) DE-IDENTIFIED: 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; OR

(B) NOT RISKY: 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) IDENTIFIABLE and WITH LIMITED IRB REVIEW: 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).

Additional information for **Exemption (3)** ***Benign Behavioral Interventions***:

(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 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 deception or concealment, 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 4: Secondary Research of Identifiable Private Information or Biospecimens

(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/biospecimens are PUBLICLY AVAILABLE; OR

(ii) DE-IDENTIFIED: 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; OR

(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 GOVERNMENT OR AGENCY using government-generated or government-collected information obtained for nonresearch activities.

Exempt 5: Federally Supported Research for Public Benefit or Service Programs

(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.

Exempt 6: Taste and Food Quality Evaluations

(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 FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt 7: Creation of Data/Biospecimens Repositories for which Broad Consent is Required

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

Exempt 8: Secondary Research using Data Repositories for which Broad Consent is Required

(8) Research involving the use of identifiable private information/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/biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); AND

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; AND

(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.