Exempt Review

Purpose

The purpose is to outline the policy and procedures for exemption in Federal human subject regulations.

Policy | Exemption Categories | Prohibited from Exemption | Procedures

Definitions

Exempt is a classification of research review which is performed by trained individuals as part of, or assigned by, the Exempt Review Committee (ERC) to ensure the protection of the rights and welfare of human subjects who participate in research. In order to qualify for exemption, a research study's activities must fall entirely within one or more Federal exemption categories, must not place subjects at greater than minimal risk, and must not involve a population prohibited from exemption.

Human subject (Participant) is a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Minimal risk means the probability of 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.

Policy

Any investigator who intends to conduct research involving human subjects, and who on the basis of the categories described below believes that research to be exempt, must submit an exempt application package to Marywood University's ERC for review and approval prior to initiation of activities. **The ERC makes the final determination about exemption eligibility.** Members of the Exempt Review Committee may exercise all of the authorities of the Institutional Review Board (IRB).

Investigators must transmit exemption applications through IRBNet, a web-based submission and management system, and include any necessary supporting materials. Except in some secondary research eligible for exemption, an informed consent form is usually required. However, documentation of informed consent is not, which means that no signatures are required from subjects on an informed consent form.

The Exempt Review Committee's website provides instructions, forms and templates, and the ERC checklist describes required documentation.

Federal Exemption Categories

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be exempted. The most frequently used categories are 2(i), 2(ii), and 4(ii). The US Office of Human Research Protections has not yet updated its Decision Charts to reflect the Revised Common Rule when aiding in review type determinations.

Category 1 - 46.104(d)(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 - 46.104(d)(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:

1. 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;
2. 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
3. This section concerning “limited IRB review” of identifiable information with disclosure risk is not being implemented at this time.

NOTE: Children are excluded if surveys, interviews, or public observations where the investigator participates in activities are involved.

Category 3 - 46.104(d)(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:

1. 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;
2. 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
3. This section concerning “limited IRB review” of identifiable information with disclosure risk is not being implemented at this time.

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 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.

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.

NOTE: Children are excluded. Wearable activity trackers or devices (e.g., Fitbit), or pulse or blood pressure monitors, do not qualify per the Secretary's Advisory Council for Human Research Protections' recommendation.

Category 4 - 46.104(d)(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:

1. The identifiable private information or identifiable biospecimens are publicly available;
2. 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;
3. 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 (HIPAA), 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

4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or collected information obtained for non-research 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*.

Category 5 - 46.101(b)(5) Research and demonstration projects that are conducted or supported by, or otherwise subject to the approval of, a Federal department or agency, 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.

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.

Category 6 - 46.101(b)(6) Taste and food quality evaluation and consumer acceptance studies:

1. If wholesome foods without additives are consumed, or

2. 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 - 46.101(b)(7) This category concerning "limited IRB review" of storage or maintenance of secondary research for which broad consent is required is not being implemented at this time.

Category 8 - 46.101(b)(8) This category concerning "limited IRB review" of secondary research for which broad consent is required is not being implemented at this time.

Prohibited from Exemption

- Prisoners, unless only incidentally included (e.g., review of records of gunshot victims, where some have subsequently become prisoners)
- Children with surveys, interviews, private observations, public observations where the investigator participates in activities, or any behavioral interventions
- Prospective interactions or interventions via educational tests, surveys, interviews or observations, where information is directly or indirectly (codes/links/associations) identifiable to the investigator AND outside disclosure would place the subjects at liability risk or be damaging to their financial standing, employability, educational advancement, or reputation
- Secondary research where information is recorded by the investigator in such a manner that subjects' identities can readily be ascertained by the investigator directly or indirectly (codes/links), or where the investigator plans to re-identify or contact the subjects
- Deception or incomplete disclosure, unless subjects are adults who are prospectively informed and agree
- Drugs, internally taken substances/foods, investigational devices, or biologics
- Prospective bio-specimen collection (e.g., tissue, blood, plasma, urine, saliva, etc.)

- Physical measures or clinical testing (e.g., skin sensors, activity trackers, biometric or sensory monitors, moderate exercise or strength testing, body composition assessment, EKG, MRI, etc.)
- Populations which may be vulnerable to coercion or undue influence, such as those with impaired decision making capacity, economically or educationally disadvantaged, etc., if their condition poses increased risk
- Fetuses or neonates

Procedures

1. The investigator reviews policies concerning human research, a submission checklist, and instructions on how to submit, which are found on the ERC's website, and/or views IRBNet Tutorial Videos (email irbhelp@marywood.edu for password).
2. The investigator completes training at www.citiprogram.org. Advisors, co-investigators and/or research assistants also complete training.
3. The investigator registers at www.irbnet.org, affiliates with Marywood University, and confirms the registration via e-mail. If applicable, co-investigators or advisors do the same. Research assistant registration is optional for most, but necessary when the RA will submit study materials on behalf of a faculty investigator.
4. The investigator downloads and completes necessary forms and templates, which are located on the ERC's website or in IRBNet's forms library.
5. The investigator and advisor, where applicable, proofreads and runs a spellcheck on all completed documents.
6. Following the written and/or video instructions for IRBNet, the investigator creates a new project, shares access to it with research team members (if applicable), applies an e-signature, has the advisor and/or co-investigators sign, and then submits it to the ERC.
7. The investigator awaits an emailed notice, which informs of the decision letter's location for download by the investigator. The ERC's decision letter describes requested actions, how to track changes, and how to submit a response via IRBNet.
8. If requested by the ERC, the investigator submits a follow-up package of modifications via IRBNet, making sure that all modifications are tracked.

9. Once approved, the ERC emails an approval notice, prompting the investigator to download the approval letter and all stamped materials (documents part of the consent process) from IRBNet. Stamped versions of documents must be used in the research unless the ERC states otherwise (e.g. online locations where a stamped version is impossible to use, such as the body of an email message or some survey platforms).
10. The investigator submits via IRBNet any requests for revisions after approval, deviations from the approved research, unanticipated problems or serious adverse events, should they occur. See appropriate policies and procedures about these topics.
11. The investigator submits a completed closure report form upon study conclusion. If activities will continue beyond a study's one-year anniversary, the investigator submits an annual check-in report form annually until closed. See Mandatory Reporting policy for report requirements.

History

05/23/2017 - Updated format, added definitions, clarified exclusions and added procedures

05/24/2018 - Updated checklist links

06/11/2018 - Corrected link to ERC

06/07/2019 - Updated as a result of the Revised Common Rule

09/30/2019 - Corrected checklist link

01/21/2020 - Corrected checklist link

09/16/2021 - Updated prohibition about incidental prisoners

10/14/2021- Clarified procedures