Exempt Review Guidance

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Contents

Introduction

Exempt human subjects research is a specific sub-set of "research involving human subjects" that does not require ongoing IRB oversight. Research can qualify for an exemption if it is no more than minimal risk and all of the research procedures fit within one or more of the exemption categories in the federal IRB regulations (see Appendix A).

Studies that qualify for exemption **must be submitted** to the IRB for review before starting the research. Pursuant to GMU policy, investigators do not make their own determination as to whether a research study qualifies for an exemption — the IRB issues exemption determinations. There is not a separate IRB application form for studies that could qualify for exemption – the appropriate protocol template for human subjects research should be filled out and submitted to the IRB in the RAMP system.

Consent for Exempt Studies

The Belmont principle of Respect for Persons generally requires that subjects be given the opportunity to choose whether or not to participate in research. For this reason, voluntary informed consent should be obtained from participants for any exempt research where the investigator will be collecting data through interaction with participants.

For exempt research studies that will collect data through interaction with participants, the GMU IRB expects that researchers provide participants with consent information that includes, at a minimum:

1. An explanation that they are being asked to participate in a research study.
2. The identity and affiliation of the researcher.
3. A clear description of the study procedures and how data will be used in the future.
4. A statement that participation in the research is voluntary.
5. Contact information for questions and concerns about the research.

Modifications to Exempt Studies

Studies that qualify for an exemption do not undergo continuing review. Additionally, modifications do not need to be submitted for exempt studies so long as the research remains minimal risk and stays within the boundaries of the exemption categories that the IRB found were applicable to the research.

It is a best practice recommendation to create a note-to-file in your research record to document the changes you make and your determination that these updates did not change the scope of the study or risk to participants.

If your proposed changes constitute any of the following, submit a track change version of the protocol you submitted to the IRB through a modification submission RAMP:

- add procedures that could affect risks to participants; or
- add procedures that do not fit within the exemption categories; or
- add new types of participants to your study that include vulnerable populations (e.g., adding children, individuals with cognitive impairments, prisoners, etc.)
- change of Principal Investigator
- additional funding source requiring IRB approval (e.g., federal or industry)

Examples of updates that would likely require IRB review:

- Removal of the consent process, or use of deception or incomplete disclosure.
- Significant changes to the recruitment procedures.
- Adding sensitive questions to a survey or interview process (e.g. questions regarding illegal activities; traumatic events such as childhood, sexual, or domestic abuse; suicide; or other probing questions that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation).

- Collection of new or additional identifiable information.
- Changes to the data storage plan which may affect confidentiality.
- Adding any new physiological measures that were not already determined to be exempt.
- Exempt studies may also be subject to the HIPAA Privacy Rule. For instance, a study involving medical record review to gather a dataset that would be eligible for Exemption Category 4 involves access to Protected Health Information (PHI) and should request a waiver of HIPAA authorization.

Restrictions on Exemptions

- Studies that are greater than minimal risk do not qualify for exemption.
- Exemptions do not apply to research with prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners. [45 CFR 46.104(b)(2)].
- Exemption 2(iii) and Exemption 3 do not apply to research with children.
- Exemptions other than Exemption Category 6 do not apply to FDA-regulated research.

Appendix A: OHRP Exempt Categories [45 CFR 46.104]

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.
Examples:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson
- A program evaluation of pharmacy continuing education

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:

1. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR
2. Any disclosure of 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. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review.

Examples:

- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program

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:

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 indirectly, through identifiers linked to the subjects; OR
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. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. (See "WORKSHEET: Limited IRB Review (HRP-319).")

(i) 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.

(ii) 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.

Example:
Healthy adult subjects are asked to take part in two two-hour-long assessments of memory, attention and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired.

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:

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

Note: Exemption Category 4 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records, or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another IRB review path will be required. Exemption Category 4(iii) only applies to the use of data (when HIPAA applies) and not to biospecimens.

Example:
A researcher is given two datasets that contain private, identifiable information. The researcher uses the identifiers to merge the two datasets but strips the resulting (merged) data of identifiers immediately after the merge and before conducting data analysis. The resulting data used for the analysis is completely de-identified with no link to identifiers.

Category 5
Research and demonstration projects which 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 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.

(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.

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 Dept. of Agriculture