Exempt Research: Researcher FAQs

[v. 09/08/2025]

1. **What is exempt research?**

   Studies participant to IRB review fall into one of three categories: Exempt, Expedited, and Full Board. Exempt research is a specific subset of studies that do not require ongoing IRB oversight based on eight categories specified in the federal regulations.

2. **What studies qualify for exemption?**

   Research can qualify for an exemption if it is no more than minimal risk and all the research procedures fit within one or more of the exemption categories in the federal IRB regulations. Please refer to the Exempt Review Guidance for more information on Exempt categories and exclusions.

3. **Who decides if a study qualifies for exemption?**

   GMU's policy stipulates that only the IRB can make an exempt determination.

4. **What does the IRB consider when reviewing an exempt study?**

   The IRB's primary objectives when reviewing an exempt study are to:

   - Confirm that the study qualifies for exemption
   - Confirm that non-regulatory institutional requirements are met, and
   - Confirm that the study plan is consistent with basic ethical principles for research

   During the review, the IRB will consider the study protocol, consent, and all other study documents. It is possible that the IRB will have questions or request clarifications in order to make the exempt determination, but any such requests are intended to support exempt determination process.

5. **If my study is exempt, do I need to obtain consent from participants?**

   If your exempt study involves interaction with participants (either in person or virtual), consent must be obtained, and the consent process should be appropriate given the participant population and the study procedures.

   Consents must include (at a minimum):

   - A statement that the activity involves research and participation is voluntary
   - A brief description of the study purpose and activities or types of questions that will be asked

- If the study involves deception, a statement informing the participants that they will be unaware of or misled regarding the nature or purposes of the research. If this statement cannot be included, the study will not be eligible for exemption
- An explanation of why or how the participants were selected – optional when evident from description of study purpose or procedures
- A statement that participants can stop participating at any time and, if applicable, skip survey questions
- A description of how confidentiality of the research data will be maintained
- The name and contact information for the investigator conducting the study and whom to contact with questions (if different)
- The IRB's contact information
- Identification of GMU – optional if evident from the context of the consent process
- A statement of financial interest, only if one exists

6. How do I submit a request for an Exempt Determination?

All submissions to the GMU IRB must be submitted through RAMP. If you believe your study may be eligible for exemption, please refer to the GMU IRB website for a copy of the Exempt Protocol Template and sample consent documents for exempt studies.

7. Do I have to submit continuing reviews or modifications for my exempt studies?

Continuing Reviews: Exempt studies do not require annual continuing reviews. When you have completed your study, you should submit a close-out request in RAMP.

Modifications: Generally, **minor modifications** to exempt studies do not require IRB review. Minor modifications do not involve any changes that would alter the exempt determination or increase risks to participants. Remember, this applies only to studies the IRB has determined to be exempt.

Major modifications to exempt studies must be submitted to the IRB for review prior to implementing them. Examples of major modifications include:

- Adding a new behavioral intervention to the study methodology or substantially changing the study procedures or aims. Note: in this context, a behavioral intervention includes the performance of a cognitive, intellectual, educational, or behavioral task or the manipulation of the participant's physical, sensory, social, or emotional environment.
- Adding any physiological procedures by which information or biospecimens are gathered (e.g., blood draw, MRI scan, etc.)

- Adding a vulnerable population to your inclusion criteria (i.e., children, adults with limited decision-making capacity, prisoners)
- Removal of the consent process, or adding the use of deception or incomplete disclosure
- Significant changes to the recruitment procedures (not including revision of already existing materials or addition of new materials that do not greatly deviate from the approved materials)
- 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 participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation). Note: if the data collection will be completely anonymous, IRB review may not be required for this type of revision. Reach out to the IRB (irb@gmu.edu) for guidance if you think this may be the case.
- Changes to the data storage plan which may affect confidentiality
- Changing the Principal Investigator (PI) or other study personnel
- Adding a new funding source

Revisions to Consent Documents: Editorial or administrative revisions to consent documents do not need to be reviewed by the IRB. However, certain revisions are not allowed to consent documents:

- Do not remove any of the required consent information.
- Do not add coercive language.
- Do not highlight payment by bold or larger type.