

FAQ for Human Research Review at GVSU

General Topics

- **When may I begin data collection for my study?**
 - You may begin data collection after your study has received approval (expedited or full board review) or determination (i.e. Exempt, not research, needs review) by the HRRC, but not before. You will receive e-mail notification and a letter will be posted on IRBnet as evidence of your approval.

- **My graduate student has to have Responsible Conduct of Research (RCR) Training. I should probably have that too. Where do I go for this training?**
 - Currently GVSU uses Epigeum for its online human and animal subjects responsible conduct of research training. For registration and access instructions, please click [here](#). HRRC recommends the Human Subjects Protection program for first time submitters (150min). If you are receiving grant funding (NSF, NIH), there may be required face to face training needed.

- **Do I need IRB approval if I am only doing a Pilot or Feasibility study?**
 - Yes! A pilot study, sometimes called a feasibility study is still a systematic investigation that may produce generalizable results. The subjects involved would need to provide informed consent, and therefore you must wait until you have project approval before beginning.

- **What if I am just working on developing my methods, nothing systematic? Do I need HRRC review first**
 - No, since you are trying to work out methodologies and techniques, is not a systematic investigation, this would be allowed prior to obtaining HRRC approval. You do not need HRRC review if no data are collected, and no subjects are involved.
 - If you are in any way unsure whether or not your project needs prior approval, please submit the Non-Human Subject Research Determination Form found on the [HRRC website](#). The Office of Research Compliance and Integrity will review your form and provide you a determination. Your unit may also have a process in place for this determination.

- **Someone told me my research is probably Exempt. Does that mean I don't have to submit anything for review?**
 - NO! Exempt is a category of IRB review. Projects that fall within the Exempt category are very low risk projects, and subjects are not identified. There must be a consent process and other steps that must follow ethical research practice. See [Policy 911](#) for more information
 - Researchers do not make the Exempt determination. This must be done by the HRRC.
 - If the project changes, then changes must be reported to the HRRC.

- **My student is going to present at Student Scholars Day. Must they have HRRC approval of their project first?**
 - Maybe. It depends on whether the project is considered covered human subjects research (that is: a systematic investigation, producing generalizable results). Some class projects may be systematic, but using only students in the class as subjects (therefore not generalizable). However, other projects may be linked to a greater project, like service learning research or an ongoing investigation. These projects would need approval. Please check with the Office of Research Compliance and Integrity for assistance to help with a determination. You can also see the helpful information on the HRRC webpage [here](#).

- **I'm teaching research methods in my class, and we are doing min-projects where we collect some data (in class). Do I need HRRC review?**
 - Probably not. The key question to answer is "Does this meet the definition of Research. Is it 1. A systematic investigation (maybe), 2. Are the results generalizable (probably not). If you have any doubts, simply contact the Office of Research Compliance and Integrity for assistance.

- **I've decided to publish. Should I get approval for my project after I have already collected the data?**
 - **Yes.** If a student or instructor wishes to conduct research on data previously collected as part of a class activity in order to validate, expand or otherwise enhance generalizable knowledge, a research protocol must be approved by the HRRC before the data may be used. There are a number of factors that come into play, so please contact the Office of Research Compliance and Integrity for assistance with existing or previously collected data.
 - In most cases this type of research will be exempt under category #4 (existing data, records or specimens), or if not exempt, then expedited category #5 (data previously collected for non-research purposes). Failure to acquire HRRC approval before utilizing data that needed HRRC approval would be considered conduct of unapproved research and is a form of research non-compliance.

- **I'm working with colleagues from another University. Are they covered under my HRRC approval?**
 - No. If you have other faculty, staff or students engaged in research with you, then you have two options:
 1. Your project would have to be reviewed and approved by the Research review committees (IRB) for both institutions. This is assuming the other institutions (like a hospital or university) have an IRB and are covered by an FWA (Federal-Wide Assurance).
 2. You may apply for a deferral at one of the institutions for single IRB review. This means that one institution's IRB defers review and accepts the review of the other. [Contact the Office of Research Compliance and Integrity](#) if you have a situation like this.

- **I have colleagues not affiliated with any FWA (i.e community organization) working with me. Are they covered under my HRRC approval?**
 - No. In this case, you must obtain an agreement from them to abide by the GVSU policies and ethics. This is known as an *"Individual Investigator Agreement"*. The application form can be found on the HRRC [website](#).

- **I'm only doing a case report. Does that need HRRC review?**
 - A case report for IRB purposes is a retrospective analysis of one, two, or three clinical cases. If more than three cases are involved in the analytical activity, the activity will constitute "research." So, if your case involves three or fewer cases, it does NOT need HRRC approval because it does not meet the Department of Health and Human Services Definition of research. [See HRRC Guidance on Case Reports](#)

- **I'm doing Ethnographic research involving the community. Does my project need HRRC review?**
 - Ethnography is the study of human behavior in the natural setting in which a population lives.
 - If the project involves **living** human subjects, utilizes a systematic investigative process and produces generalizable results, then YES it must be reviewed by the HRRC.
 - If you have any doubts, always check with the Office of Research Compliance and Integrity.

Informed consent

- **Are there any examples of what information I need to have on a consent document?**
 - Yes! Guidelines for constructing an informed consent document can be found [here](#).

- **If my protocol is determined to be exempt, does that mean I don't have to have any consent process?**
 - NO. You must have a process of consent with all research with humans. The consent process may not include an informed consent form, but there must be a process in place by which subjects are informed of the project they are participating in as well as any risks and benefits. They must agree to have their data used for research purposes.

- **Do participants always have to sign an informed consent document?**
 - No, in some cases signed informed consent may actually increase the risk of the study by identifying the participant. The HRRC committee may grant a waiver of documentation of consent.

Some things they will consider:
 1. the research must involve no more than minimal risk to the subjects;
 2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. the research could not practicably be carried out without the waiver or alteration; and
 4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

- **Do I have to always obtain written permission from parents for children to participate?**
 - Most of the time the answer will be YES.
 - However, for some research that is done within the classroom setting, using normal educational practices, the child may be participating in activities they would normally do within the class. Passive assent may be implied, or the researcher may offer an "opt out," where the parent can choose not to have their child participate. Each case will be different, so make no assumptions! Check with the Office of Research Compliance and Integrity.

- **What is the difference between “Consent” and “Assent”?**

- Consenting is a process where the researchers clearly communicate with the participant ensuring that the individual understands expectations. It is a conversation and the consent document is a record of this conversation. **Consent** may only be given by individuals who have reached the legal age of consent (in the U.S. this is typically 18 years old, but it may differ in other countries).
- **Assent** is the agreement of someone not able to give legal consent to participate in the activity. Work with children or adults not capable of giving consent requires the consent of the parent or legal guardian and the assent of the subject.

Documenting assent by having the child sign an assent form is usually a procedure that is incorporated for children age 7-17. When documentation is not required, the IRB requires that the investigator conduct the assent process through a verbal script and the IRB will review the script of what will be said during the verbal consent process

Subject Risk

- **I’m only giving subjects a survey. That’s always minimal risk right?**

- Not necessarily. The HRRC will focus on risks that are directly related to participation in the research components themselves.

- **What does it mean to have “minimal risk”?**

- Risk will also help determine the level of review (Exempt, Expedited, Full Board). Risk comes in many forms. It may be physical (injury, soreness, falls), it may be psychological (questions about sexuality, past abuse, PTSD), and/or financial (questions about your boss that might get you fired, questions about underage drinking habits).
- Two main characteristics influence the nature of assessing overall risk:
 - i. probability of the harm occurring
 - ii. magnitude (severity) of the harm
- The magnitude of potential harm is the summative measure of its severity, duration and reversibility. Thus, a research protocol with a low probability of harm occurring, but a high severity of harm (if it occurs), may be assigned a greater than minimal risk (e.g. questions about depression and mental health disorders, sexual abuse, violent crimes, criminal behavior, opinions about employer..). Research activities that might trigger higher risk may include: deception, coercion, use of vulnerable populations (pregnant women, cognitive disability)

Not Research

- **Someone told me my project was probably not human subjects research, should I submit to the HRRC anyway?**
 - Ethics dictate that if you don't know, then get help from the Office of Research Compliance and Integrity. You do not want a mistake leading to non-compliance.
 - However, it is the policy of GVSU and the HRRC that GVSU faculty researchers are permitted to determine whether a proposed activity of their own, or of a student whom they are supervising as research advisor, constitutes research as defined under the federal regulations. The HRRC is available to assist any GVSU faculty, staff or student in properly making this determination. A worksheet to assist you is found [here](#).
 - Please realize that a study may be considered research, but not **covered human subjects** research. The determination of whether the research is **exempt** from the federal regulations may only be made by the HRRC. All human subjects research including exempt research must be reviewed and approved by the HRRC before recruitment and data collection may start. Criteria for what exempt research consists of can be found [here](#).

Exempt Application

- How do I know if my project meets the exempt determination?
 - You should start by using the review decision making tools provided [here](#). These will help explain the types of research within each of the categories of review.
 - The Office of Research Compliance and Integrity have Guidance documents for each of the levels of review, along with the application form. Choose the form you feel best fits the level of review. Please see the [HRRC webpage](#) for more details.
 - The HRRC has the final decision on the level of review, so things may change. You are always encouraged to contact the Office of Research Compliance and Integrity if you have questions.

Expedited Application

- **Where do I get started with my application?**
 - If you are sure that expedited is the level of review, then start with the [Guidance document](#) and the application on the HRRC [webpage](#). The guidance document explains each of the steps in the application (the form not so much). So don't skip the guidance! A lot of delays in reviews can be avoided by simply following the guidance document.

Full Board Application

- **My project was reviewed and they said I needed a full board review. Why?**
 - A review of your project has indicated that study does not qualify as exempt and the level of risk is above “minimal”. Therefore the entire board will serve as reviewers. The board will then convene at the next monthly meeting to discuss the project. You will probably be invited.
 - When you come to the meeting, be prepared to explain the methods and design of the study, with careful attention to describing any risk. You will be provided the review remarks of the committee prior to attending.
 - Written responses to the committee’s questions will be very helpful at the meeting.
 - Remember, the members are not experts in your field! Be ready to explain the study in a manner that a non-expert can understand!

Submission process: IRBnet

- **Are there any guides to help me submit to IRBnet?**
 - Yes! You can find the IRBnet Instructions on the HRRC webpage [here](#).
- **What is “continuing review”?**
 - Protocols that are Expedited or Full Board are required to report progress and any activities to date (number recruited, withdrawals, etc.) in order to maintain their approval. This is done annually or every two years depending on the committee recommendation. If continuing review is not completed, and the approval expires, you cannot collect any data (or you are in non-compliance).
 - Instructions for submitting a continuing review can be found [here](#).
- **What if I want to make changes to my study? Can I do that?**
 - If a proposed modification to an **exempt research protocol** does not alter the level of review required (i.e., does not require upgrading to expedited or full board review), and does not (i) increase the risk-to-benefit ratio, or (ii) substantially enlarge the scope of the study, the researcher may implement the change without prior approval from the HRRC.
 - For an **expedited or full board protocol** where the methods, recruitment or design of the study is going to be changed, you must report these changes to the HRRC in order to have those changes approved.
 - Complete a “Change in Approved Protocol” form. The instructions for doing this can be found [here](#).

- This may also apply to a project previously labeled “non-research”, but changes made now mean that the project IS research (in this case you will need to submit a complete application).
- **I need to close my project, where do I go for that?**
 - Instructions can be found [here](#). You will need to submit the closure form through IRBnet.

Review process

- **Why do I need an authorizing signature before my project is reviewed?**
 - All PI’s MUST have the signature of the Authorizing Official (AO) before their project can be reviewed by the HRRC.
 - The AO is typically the supervisor above the level of the individual (e.g. department head, associate dean, dean). These individuals are charged with reviewing the proposal for:
 - Scientific merit
 - Feasibility (cost, equipment, time)
 - Adherence to any standards set independently by the department or college
 - You are advised to let the AO see your proposal BEFORE you submit, so they can suggest any changes.
 - After you have signed your proposal in IRBNet, YOU must share the proposal with your AO in order for them to sign.
 - If you do not know who your AO is, contact the Office of Research Compliance and Integrity.

- **What are the most common issues reviewers encounter when reviewing proposals?**

Incomplete materials. The HRRC is tasked to identify the degree of subject risk and any benefits in the design of the study. If you have not provided enough information about the design of the study, we cannot make any determination.

Informed consent and the consent process. There must be a process identified for consent, and if there is an informed consent form used, it must have the essential elements (see the [informed consent guidance document](#)). Also, it must be written for the lay person; this means written at the 8th grade reading level.

- ***Use of technical jargon.*** Proposal descriptions written for an expert in their field make it difficult for reviewers to read and understand. Remember, the reviewers are faculty and community members from many different fields. You need to describe the project so that

a lay reader will understand what you are doing. This will go a long way to avoid questions.

- **Hint:** did you know you can get readability statistics for your document in MS Word? Just click on File: Options: Proofing- and look for a box labeled “readability statistics”. Check that box and then run your spell check!

Other items often missing:

- Evidence of RCR training (post your certificate)
- Missing surveys or other tools used in the study

- **Why does it take 3 weeks or more to hear about my project proposal?**

There are approximately 80-100 proposals, continuing reviews, project closures, and other submissions each month. Including revisions to protocols, the numbers almost double. These are handled by a Human Research Review committee of 15 members and a staff of 2 individuals. HRRC members are given 5 working days for exempt reviews and 8 days for expedited reviews, followed by reviews of their comments by the HRRC chair. While we work as fast as we can, we must consider federal regulations as well as subject safety. The more clarity in your materials, the faster the review will be completed.

- **Why is the committee asking about the design of my study? What does that have to do with a review?**

- In order to accurately assess the risks and benefits of the study, the IRB needs to understand the methodology of the study, equipment used, treatments, surveys etc. In some cases the risks may be minimized by design changes, and these suggestions would fall within the role of the IRB when it relates to subject risk.

- **Why is the IRB asking about MY qualifications? I have a PhD!**

- Federal guidelines require that all IRBs “...need to assess the investigator’s training and experience specifically related to the proposed study, particularly if the proposed research involves higher risks, vulnerable subjects, or novel technologies. For such proposed research, the IRB’s determination that the investigator is qualified may need to include a review of the investigator’s previous specific experience as demonstrated by recent presentations or publications, and prior clinical experience with the test article or study-related procedures (DHHS Guidance for IRBs).” This information is to ensure subject safety.

- **What is the best advice for preparing my submission?**

Look on the HRRC website and find the Guidance Document for the submission you plan (either Exempt or Expedited/Full board). These documents are regularly updated, and explain the steps of the process of completing the form. Use them! Many errors can be avoided by simply following the guidance documents provided. If you have any questions, please do not hesitate to contact the Office of Research Compliance and Integrity at (616) 331-3197 or rci@gvsu.edu.