

FERRUM COLLEGE IRB GUIDELINES

There are times when a student research project must be reviewed and approved by the IRB, though there are other times when student and class projects may qualify for a waiver. Class projects utilizing a waiver must still be on file with the IRB.

Projects that Require IRB Review: Projects Producing Generalizable Data (p. 3)

When the goal of the student project is to contribute to generalizable knowledge (i.e. student plans to make generalizable assertions with the data, the student plans to publish and/or disseminate the results from the study to a public audience, making generalizable statements about the data), federal regulations require that this research be reviewed and approved by the Institutional Review Board (IRB) prior to initiation, regardless of the source of funding and regardless of its federal status as an exempt, expedited, or full review project. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB. The IRB further requires that all student research activities be supervised by a faculty member.

Independent Research Projects

Independent projects are those that the students and/or faculty member engage in systematic data collection with the intent to produce generalizable knowledge, which often includes data dissemination. Honors research projects, projects engaging in research through partnering with community organizations with a goal of producing generalizable data, grant funded research, and other student/faculty research projects are considered research (45 CFR 46). These projects, which are intended to draw conclusions, inform policy or generalize findings to a larger body of literature, are considered research. While these projects are often published and/or presented, they do not have to be to be considered research. When generalizable knowledge is the intent, *IRB approval is required. If the student project meets the criteria listed above, IRB procedures should be followed as review and approval is required (see page 3 for IRB Review Guidelines).*

Projects that May Qualify for a Waiver: Student and Class Projects (p. 6)

Some types of student research-related activities may be waived from IRB review above and beyond faculty supervision, because their goal is educational and *not the* dissemination generalizable knowledge. Ferrum College supports undergraduate research projects using human subjects, some of these are conducted primarily to allow the student to learn how to conduct research. To determine whether or not your project meets the criteria of a waiver, please consult the following flow chart.

Research with Human Subjects Flow Chart

This chart provides guidance as to how to proceed with different types of research at Ferrum College.

Is the intent of the project to produce generalizable results? Do the investigators plan to publish the results of their investigation?

→ **Yes** (to either question) → **IRB Review Required. Please follow IRB Review Guidelines on p. 3**

No
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Is the project a senior capstone project or honors thesis that involves research (*this typically means the goal is to produce generalizable research*)?

→ **Yes** → **IRB Review Required. Please follow IRB Review Guidelines on p. 3**

No
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Is the project for a class assignment where the primary purpose of the assignment is to learn the methods and procedures of research?

→ **No** → **IRB Review Required. Please follow IRB Review Guidelines on p. 3**

Yes
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When the Student/Class project data is shared, will it be limited to the classroom context and/or population the data was collected? Will the data be destroyed at the end of the project with no further use?

→ **No** (to either question) → **Contact IRB For Guidance. irb@ferrum.edu**

Yes
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Does the project involve greater than minimal risk (that which is ordinarily encountered in daily life)? Does the project ask questions about sensitive topics (sexual orientation, rape, sexual conduct, substance use, mental health concerns or traumatic experiences)? Does the project involve protected populations (children, pregnant women, fetuses, prisoners, individuals who are mentally disabled)?

→ **No** (to all questions) → **IRB Review is likely not required. Please review the Guidelines for Student/Class Projects on p. 6**

Yes (to any question)

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IRB Review Required. Please follow IRB Review Guidelines on p. 3. If you have questions on whether your project requires IRB review, please contact the IRB at irb@ferrum.edu

IRB Review Guidelines for Researchers

For IRB approval, researchers must complete a **IRB Protocol Form**. The main purpose of the IRB Protocol Form is to educate the members of the Institutional Review board as to the nature of your research. Therefore, include as much detail as is necessary to allow the members of the IRB to make an informed decision. The chairperson of the IRB is available to consult with you as needed. Please do not hesitate to contact the IRB at irb@ferrum.edu. *The type of review undergone by the IRB depends on the amount of risk posed by your study. Below are some general guidelines. Please see the IRB Protocol Form for additional information.*

Full Review

All research is presumptively in this category unless it meets certain exceptions as described below.

Expedited Review

Some research may be reviewed by the chair of the IRB or by one or more experienced reviewers designated by the chair from among members of the IRB, if the research falls into certain categories defined by the federal government and if, in the discretion of the chair, review by the full committee is not necessary.

Research activities that (1) present no more than minimal risk to human participants, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be considered of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human participants. Please see the "IRB Protocol" for additional details on categories, if necessary.

Expedited Research Categories

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture according to guidelines posted in the "IRB Protocol".

- Prospective collection of biological specimens for research purposes by noninvasive means.
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Clinical studies of drugs and medical devices that meet conditions explicitly listed in the “IRB Protocol”.
- Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

Exempt Review

Though the following categories of research are exempt from review by the full IRB, a Protocol Submission Form must be completed and on-file with the IRB prior to the start of data collection. The study will be reviewed to ensure it meets the criteria for an exempt review

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

Exempt Research Categories

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless** : (i) Information obtained is recorded in such a manner that the human participant can be identified, directly or through identifiers linked to the participants; **and** (ii) any disclosure of the human participant's responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph 2, **if**: (i) The human participants are elected or appointed public officials or candidates for public office; **or** (ii) federal statutes(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participant.
- Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs (e.g., social security, welfare, etc.); (ii) procedures for obtaining benefits or services under those programs; (iii)

possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- 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 U.S. Department of Agriculture.
- Student projects that are part of a class assignment and do not involve physically or psychologically invasive, intrusive, or stressful procedures; or, in the judgment of the instructor, do not have the potential for placing the participants at more than minimal risk, do not require review by the IRB. Minimal Risk is defined in CFR Title 45, Part 46 as "the probability 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." Student research, including classroom and independent study projects, that may place the participants at more than minimal risk is subject to IRB review. Special populations including pregnant women, fetuses, prisoners, mentally disabled, economically or educationally disadvantaged or minors are considered vulnerable research participants and, all projects involving such participants must be reviewed by the IRB. **Please see Class Projects Guidelines if your student projects fall into this category on p. 6.**

Student and Class Projects Waiver Guidelines

Some types of student research-related activities may be waived from IRB review above and beyond faculty supervision, because their goal is educational and *not the* dissemination generalizable knowledge. Ferrum College supports undergraduate research projects using human subjects, some of these are conducted primarily to allow the student to learn how to conduct research. After completing the flow chart (p. 2) please review the following guidelines to ensure your project meets the waiver criteria.

Student and Class Projects: Research Methods Training/Curriculum

Student and class projects done as part of a *research training curriculum* by which the *overriding purpose of the project is a learning experience* generally do not meet the federal definition of research. These types of projects may be waived from the review of the IRB ***if the following conditions are satisfied:***

- 1. The project involves minimal risk to subjects** (i.e., when “the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”). To protect participants, projects involving videotaping do not qualify for a waiver as such projects potentially involve more than minimal risk to participants.
- 2. The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed.** Any interview, survey, or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but not limited to, any of the following sensitive topics *requires IRB approval:*
 - Sexual orientation, incest, rape, sexual molestation, deviant sexual behaviors or attitudes regarding sexual conduct (pedophilia, bestiality, etc.), practices of contraception, abortion, and/or pregnancy
 - Substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics, and any prescription medication legally or illegally obtained
 - Questions regarding mental health (e.g., suicide depression, obsessive- compulsive behaviors including, but not limited to, drug use, underage drinking, gambling, eating disorders, etc.)
 - Traumatic experiences of an individual (e.g., being a victim of violence including child abuse, senior abuse, war or combat experiences of veterans)
- 3. The project does not involve persons from certain vulnerable populations as participants.** For the purposes of classroom research, vulnerable populations who may not be included are: pregnant women, fetuses, children (under the age of 18 years old), prisoners, persons at high risk of incarceration or deportation, or mentally disabled. Projects involving such subjects ***require*** IRB review and submission of a protocol for approval prior to beginning the research. *Please note: some of Ferrum College’s student population are minors.*
- 4. The project must involve the voluntary participation of individuals without any coercion or pressure being placed upon them by the researcher.** It is highly recommended that instructors/students consider providing a consent document to participants and fully informing

them of the research in which they will be taking part.

5. The results of the project will never be distributed to professional conferences, journals or books, etc. However, the student may present findings on campus or off campus to the individual(s) directly involved in the research *if the purpose is to educate the student in the academic process and not to disseminate generalizable knowledge*. If the possibility exists that either the instructor or the student would consider disseminating the data as generalizable knowledge, the research must be submitted for IRB review. If after collection of data the instructor or student deems the results to represent generalizable knowledge worthy of dissemination, the instructor should immediately submit a protocol describing the method and results to the IRB for review/approval. Please note that approval under such circumstances is not guaranteed and any data collected under a classroom projects exclusion may not be disseminated prior to IRB approval.

Examples of Student and Class Projects:

- a. A student presentation to fellow class members sharing the results of a voluntary survey taken of Ferrum College students over 18 years of age concerning a non-sensitive topic area would qualify for a waiver.
- b. Interviewing individuals for a project on a non-sensitive topic where the results will only be shared with the faculty member teaching the class and fellow class members would qualify for a waiver.
- c. Student and class projects involving a program evaluation, quality assurance, or needs assessment for a third party, where the collected information will remain in the classroom and only be disseminated to the third party agency may qualify for the waiver, depending on the situation.

Note: Student and class projects pertaining to sensitive information (as identified in section 2 above), involve more than minimal risk (section 1), use vulnerable populations (section 3), involve coercion (section 4) or whose intent is to produce generalizable knowledge (section 5) must be reviewed by the IRB (see IRB Review Guidelines p. 2)

Responsibility for Oversight of Student Research Projects involving Human Subjects

It is the responsibility of the faculty member to evaluate whether or not the project needs to be reviewed by the IRB (see above; feel free to contact the IRB for questions or clarification). Once IRB eligibility is determined, the faculty member has responsibility to ensure that the class project is conducted according to the ethical standards of the relevant discipline.

Projects requiring IRB review (for additional guidelines see p. 2)

Projects that require IRB review require first that both the faculty member supervising the projects and the students complete the Protecting Human Participants training (<http://phrp.nihtraining.com/>). Secondly, the **IRB Protocol Form** be completed for each individual project by the student (see FaCET). These forms must be collected, reviewed and approved by the faculty member prior to being submitted to the Ferrum College IRB. Once approved, the faculty member should forward the forms to the IRB for review (irb@ferrum.edu) and eventual approval. All information pertaining to the IRB process can be found on FaCET. Please note the IRB approval process often takes two weeks, and may take longer if extensive changes to the protocol are required.

Student and Class Projects which Qualify for a Waiver

1. Faculty members are responsible for complete oversight of all research activities, including Student and Class Projects that meet the criteria for a waiver, ensuring that the project is being conducted of human subjects research and their individual discipline.
2. Faculty members providing supervision of human research must complete the Human Research Training (<http://phrp.nihtraining.com/>) and maintain active certification. Faculty members are *strongly encouraged* to have their students complete this training as part of the research training process and maintain copies of the students' certifications.
3. Faculty members should train students in the conduct of ethical research and supervise project design. Several tools are available on FaCET to assist with this process, including a **Student Project Approval Application** which students can use to gain faculty approval of their project, and a modifiable informed consent form.
4. Faculty members should complete a **Student and Class Projects Waiver Form** and submit to the IRB. This form provides notification of the project to the IRB committee of the project(s) and ensures the faculty member has accepted responsibility for the ethical conduct of the projects. Once submitted, it is always the responsibility of the faculty member to:
 - a) Remind students that from the participant's viewpoint, giving out personal information does not differ for a student/class research project or an official IRB-recognized research project. Personal information is personal information. Faculty members should advise students to identify the project to participants as a class assignment and be sensitive to the personal nature of the obtained information. Students should be reminded that data from human subjects should not contain any personal, identifying information whenever possible.
 - b) Students should inform participants that data will be destroyed after their assignment or class project is completed. Faculty members should develop a plan with their students to destroy the data.

c) All student/class projects should include informed consent language that closely follows the guidelines.

d) Review student's plans for the research proposal. An example research application is available for faculty modification to assist with this process. This helps train the students in the research process and allows faculty members to ensure the project(s) are being conducted ethically. Faculty members should review these plans for improvement in both design and protection of human subjects.

e) The IRB is available to give feedback on any proposed student/class project not meeting the definition of research, even though the IRB would not officially act on the project. Contact the IRB at irb@ferrum.edu.

Classroom Research Project Checklist

This document is intended to assist Ferrum College faculty in assessing whether classroom research projects may be excluded from review and approval by the Ferrum College Institutional Review Board (IRB). All items below must be satisfied for classroom projects to proceed outside of IRB review.

For questions relating to such projects, we encourage instructors to contact IRB committee at irb@ferrum.edu.

- The research project is to be performed by students enrolled in a course at Ferrum College as a requirement for completion of the course.
- The overriding and primary purpose the project is as a learning experience in the methods and procedures of research.
- The instructor is fully aware of all aspects of the research project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.
- There is no intent on the part of the instructor or student to produce generalizable knowledge or to disseminate the findings beyond presentation to instructors or peers in a Ferrum College classroom setting.
- The project involves minimal risk to subjects (i.e., when "the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").
- The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed.
- The project does not involve persons from vulnerable populations as participants.
- The project involves the voluntary participation of individuals without any coercion or pressure being placed upon them. The instructor/students have considered whether a consent document should be provided to participants.