

Student Project or Human Subjects Research? Guidance for Faculty and Students

This document was developed to provide guidance to faculty and students with determining whether a student project is considered research under the federal regulatory definition, and therefore requires review and approval by the Human Research Protection Program (HRPP) or the Institutional Review Board (IRB). It includes details on the different types of IRB submissions, the review process, and examples of each. If you have questions about this guidance or how it should be applied please contact the HRPP by sending an email to irb@vt.edu

Student projects can be defined as a series of assignments or tasks that, when merged, approach a defined goal to meet course objectives. Student projects come in many forms and can span just a few days, weeks, an entire semester, or multiple semesters. Student projects are designed to accomplish the pedagogical goals of a course or degree program.

Research projects are generally defined as systematic investigations designed to create generalizable knowledge. Student projects can be research if they are designed to add to the knowledge in a particular field. Theses and dissertations are common examples of student projects that are considered research under the federal definition.

Definitions

Research: Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Generalizable in this context means universally or widely acceptable; relates to drawing general conclusions, informing policy, or findings and/or information that go beyond a single individual or an individual program. There are certain activities that are not considered research as defined by the Department of Health and Human Services (HHS). Please see [HRP-001.1](#) for additional information on those activities.

Human subject: A human subject is a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information about a person or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention: Intervention refers to procedures by which information or biospecimens are gathered (for example, questionnaire or venipuncture) are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Interaction refers to communication or interpersonal contact between investigator and subject.

Private Information: Private information refers to information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking

place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable Private Information: Identifiable private information refers to private information for which the identity of the subject is known, either through identifiers associated with the record or when the identity of the subject can be readily ascertained by the investigator.

Identifiable Biospecimen: Identifiable biospecimen refers to a biospecimen for which the identity of the subject is known, either through identifiers associated with the record or when the identity of the subject can be readily ascertained by the investigator.

Student Project: A student project is a task, or series of tasks, that are required as part of the course curriculum or degree requirements and meet course and/or degree objective(s). The outcome of the project is not intended to create generalizable knowledge. Often, the main objective of the project is to teach the student(s) how to conduct research and gain experience with the IRB process. The scope of the project generally does not go beyond the boundaries of the assignment, but in some instances it can.

Capstone Course/Senior Design Project: A capstone course is a key component of the major requirement that generally takes place over the course of two semesters. The first semester focuses on the design and development of the project and subsequent semesters focus on the project's implementation or execution.

Additional Considerations

If the professor has an interest in giving the students the opportunity to experience the IRB review process please contact the HRRP at irb@vt.edu. The HRPP has developed resources that will give students exposure to the requirements for conducting human subjects research as well as the expectations for the HRPP review. In addition, HRPP staff are available to give class presentations and facilitate Q&A sessions.

Student projects that involve development of biomedical devices are likely to be subject to FDA regulations. The development and review for these projects can be complex and time consuming (and often requires full IRB review), **so it is important to consult with the HRPP in the early phases of development to develop a timeline for review.**

How to Determine if a Student Project is Human Subjects Research

Start by applying the definitions from the previous section.

1. Does the project meet the definition of research (e.g., is it a systematic investigation designed to create generalizable knowledge)?
 - a. Yes – go to the next question

- b. No – Stop, no further action is needed unless the scope or purpose of the project changes
 - c. Not sure – Send an inquiry to irb@vt.edu or request a human subjects research determination through the [IRB protocol management system](#)
2. Does the research project involve human subjects (e.g., does it involve interaction or intervention with humans or does it acquire identifiable data or information about people)?
- a. Yes – Start a new protocol in the IRB protocol management system
 - b. No – Stop, no further action is needed unless the scope or purpose of the project changes
 - c. Not sure – Send an inquiry to irb@vt.edu or request a human subjects research determination through the protocol management system

Key Differences

Research	Student Project
<p>The intent is to use commonly accepted scientific methods to collect data and information that will result in conclusions that have general applicability; there is a specific hypothesis or a question the researcher is trying to address; the impact of the research goes beyond the participants</p> <p><i>See Case Study E3</i></p>	<p>Results will not be generalizable outside of the context of the class project or assignment; the knowledge gained will not have an impact on a larger scale; small sample sizes; very specific information – applies to a specific program or activity at Virginia Tech and cannot be applied at other academic institutions</p> <p><i>See Case Study E2</i></p>
<p>Not required for a grade; would be doing the project regardless of the assignment; will be going beyond of the scope of the assignment; the student and/or instructor plans/intends to analyze the results and contribute to the scientific literature in the field</p> <p><i>See Case Study E6</i></p>	<p>Required for a grade; would not be doing the project if it were not assigned; will not go beyond the scope of the assignment and/or course</p> <p><i>See Case Study E1</i></p>
<p>The primary goal is to contribute to generalizable knowledge regardless of whether the activity provides the student(s) training or experience in applying research methods</p> <p><i>See Case Study E6</i></p>	<p>One objective or goal of the project (or course) is to provide the student with experience in applying research methods</p> <p><i>See Case Study E4 and E5</i></p>
<p>Requires HRPP or IRB review, a <u>submission is required</u></p>	<p>No HRPP or IRB review is required, <u>no submission is required</u></p>

Additional considerations for faculty conducting research related to student assignments or projects:

- If the results of the assignments or projects are likely to lead to generalizable knowledge and the results will be used to inform teaching practices, the project most likely meets the criteria for research involving human subjects, so HRPP or IRB review is needed.
- If the class assignment is related to new teaching methods or strategies and the impact and outcomes would add value to the discipline or be informative to teaching methods and strategies, the assignment most likely meets the criteria for research involving human subjects and HRPP or IRB review is needed.

Case Studies

E1: A professor is teaching an undergraduate course on ethnographic research methods. For the oral history section, each student is required to contact a veteran of the Vietnam War and ask them to tell the story of their first three days in the war zone. Each student turns in the assignment, is graded, and the professor retains the assignments per usual practice. *This is a class project and does not need HRPP or IRB review.*

E2: A professor is teaching an undergraduate course on ethnographic research methods. For the oral history section, each student is required to contact a veteran of the Vietnam War and ask them to tell the story of their first three days in the war zone. Each student turns in the assignment. The graduate teaching assistant (GTA), who is looking for a thesis topic, is grading the papers and notes several overlapping themes. They ask the professor if they can use the assignments as part of their thesis. The professor agrees, but suggests that the GTA reach out to the HRPP for guidance. After review, the GTA is advised that the content of the oral histories will not develop or contribute to generalizable knowledge, and that they can be used with the professor's agreement (with advice that a research determination form be submitted, and that these course artifacts be de-identified before use). *This is not research and does not need HRPP or IRB review.*

E3: A professor is teaching a graduate course on ethnographic research methods. For the oral history section, each student is required to contact a veteran of the Vietnam War and ask them a specified series of questions about the first time they encountered enemy fire (the class develops the list of questions as another learning activity). The professor plans to use the results to write a book chapter about first combat experiences. The professor thinks that they will be able to draw generalizations about these experiences in the book chapter. *This is human subjects research and will require HRPP or IRB review. In addition, each of the graduate students is engaged in the research, and will need to be listed in the IRB protocol's personnel section.*

E4: A student plans to initiate a project to partially fulfill the final examination requirements for graduation. The project involves the development and administration of a survey instrument, data collection, data analyses, and a final written report of the results. The intent of the project is to expose the student to a learning experience in an area of personal interest. There may be an opportunity for

future conference or journal publication, but the primary goal of the project is to satisfy graduation requirements. *This is not research and does not need HRPP or IRB review.*

E5: A professor has a research project funded by a new biomedical company that wishes to explore new materials for 3D-printed prostheses. The professor assigns a graduate materials engineering class to design an experiment to determine which materials are best suited for prostheses. At the end of the semester, the professor summarizes the results in a report to the company. *Although the results may be generalizable, no humans are involved, this is not human subjects research and does not need HRPP or IRB review.*

E6. The professor is ready for the next phase of testing for the 3D-printing of prosthetic parts. In the next semester, the professor assigns students in a graduate course to find forearm amputees who are currently using prosthetics printed from 3D-templates from a public database. Each participant will be provided with a new, identical prosthetic, but made of one of the two best new materials identified in the previous phase of the study. Each participant will be surveyed as to preference after one month of use of the new prosthetic. The results are used for a report for the sponsoring company. One graduate student gets permission from the company to conduct additional performance testing with the same participants for their thesis. *This is human subjects research and will require HRPP or IRB review. In addition, each of the graduate students is engaged in the research, and will need to be listed in the IRB protocol's personnel section. The thesis research will require a separate protocol submission, as the risks are likely to be greater.*

Responsibilities

1. Faculty and Advisors – Provide guidance and assistance to students in the following areas:
 - a. Help identify the research objectives and the scope of the project
 - b. Serve as principal investigator for student projects
 - c. Complete human subjects research training requirements and keep it current
 - d. Upload a current CV or resume into the IRB protocol management system and upload an updated version every 3 years
 - e. Review the design of the proposed activities and ensure they adhere to scientific and ethical norms
 - f. Have a basic understanding of the ethical and regulatory requirements for conducting human subjects research
 - g. Ensure that the appropriate approvals are in place prior to the initiation of any human subjects research activities
 - h. Ensure that human subjects research is conducted in accordance with the approved protocols
 - i. Obtain approval for any changes to the research prior to the implementation (except for changes to eliminate potential hazard/harm to participants)
 - j. Ensure the ethical conduct of all research activities
 - k. Ensure that there are appropriate protections in place for maintaining privacy and confidentiality

2. Students
 - a. Complete human subjects research training requirements and keep it current
 - b. Upload a current CV or resume in the IRB protocol management system and upload an updated version every 3 years
 - c. Have a basic understanding of the ethical and regulatory requirements for conducting human subjects research
 - d. Ensure that the appropriate approvals are in place prior to the initiation of any human subjects research activities
 - e. Ensure that human subjects research is conducted in accordance with the approved protocols
 - f. Obtain approval for any changes to the research prior to the implementation (except for changes to eliminate potential hazard/harm to participants)
 - g. Ensure the ethical conduct of all research activities
 - h. Ensure that there are appropriate protections in place for maintaining privacy and confidentiality
3. Departmental Reviewer/Human Subjects Advisors
 - a. Be familiar with the regulatory requirements for the various types of reviews and advise faculty and students accordingly
 - b. Review submissions to ensure that all materials are included (consent form, recruitment flyers, data collection instruments, etc.) prior to sending forward for HRPP or IRB review
4. HRPP
 - a. Be available to consult with the principal investigator and the student to provide guidance as needed
 - b. Provide resources on how to complete the protocol and other study-related documents
 - c. Ensure that the proposed human subjects research activities fulfill the applicable federal and state regulations as well as university policies
 - d. Review submissions and provide feedback to the principal investigator and student in a timely manner
5. IRB
 - a. Protect the rights and welfare of research participants by approving projects that meet the regulatory criteria for approval
 - b. Document any interactions with the principal investigator and student (conversations, Zooms, emails, etc.)

Frequently Asked Questions

Q. What if I want to analyze the data I collected as part of a class project and present the results at a conference or publish in a journal?

A. Data that were collected for a class project can be analyzed and presented at a conference and results can be published. If the presentation or publication does not contribute to generalizable knowledge or does not include human subjects, review by HRPP or IRB approval is not needed. The original data collection must meet the definition of a class project.

Q. My project was not designed to be generalizable, but the findings were intriguing and I would like to expand the activities to collect and analyze more data. I think this expansion might make it research. What should I do? Can I use the data I previously collected?

A. Submit a request for a research determination via the IRB protocol management system. If the project is determined to be human subjects research, you will need to submit an existing data protocol and describe why and how the data were collected.

Q. I don't necessarily plan on contributing to generalizable knowledge, unless the results are significant in some way, at which point I'd like to disseminate more broadly. What should I do?

A. If you plan to contribute to generalizable knowledge in any part of your project, you should submit a request for a research determination via the IRB protocol management system and clearly describe the purpose of the data collection project. Generally speaking, projects that have any plan for creating generalizable knowledge, including the project in this example, are considered to be research by the federal definition. If your project is determined to be human subjects research, you will be required to submit a protocol.

Resources

HRPP Website: <https://www.research.vt.edu/sirc/hrpp.html>

Questions and inquires can be directed to irb@vt.edu

Training Requirements and Instructions: <https://www.research.vt.edu/sirc/hrpp/training.html>

Protocol templates: <https://www.research.vt.edu/sirc/hrpp/resources/templates.html>