



**Student or Trainee Research and Course Projects Involving
Human Subjects – Standard Operating Procedures**

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1. Overview

Purpose

Federal regulations and Drexel University policies require Institutional Review Board (IRB) approval for research with human subjects. This applies whether the research is conducted by faculty or students, by individuals, or a group. *Failure to obtain proper approval in advance may jeopardize your data, prevent publication of the results, and place researchers and Drexel University in violation of federal regulations.* The IRB does not have the option of granting “retroactive” approval after human subjects research is completed, including research determined to be exempt. Investigators should submit an application to the IRB for a formal determination if there is any doubt if a protocol requires IRB review. If there is any intent to disseminate findings or publish results of student research, IRB review is recommended as publication gatekeepers will often request this documentation.

Scope

These procedures apply to student and trainee researchers, including when research involving human subjects is part of a course project. Student researchers include undergraduate, graduate, and post-doctoral level researchers. See ORI-002 Principal Investigator Eligibility and Responsibilities and ORI-004 Drexel Research Agent Eligibility and Responsibilities.

2. Student or Course Projects that Qualify as Human Subjects Research

When class projects and student or trainee research projects in the form of directed or independent research, including projects that result in undergraduate honors theses, Masters theses, or Doctoral dissertations qualify as human subjects’ research as defined by [45 CFR 46.102\(l\)](#), submission to the Drexel University IRB or reviewing IRB is necessary.

Student researchers should submit an application to the IRB through the electronic IRB management system. In order to serve as Principal Investigator (PI), student researchers must have a Drexel University Faculty Mentor listed in their IRB application. Please see additional Drexel HRP SOP for Investigator Responsibilities and ORI-002 Principal Investigator Eligibility and Responsibilities for more information on who may serve as the PI on trainee research projects. Authorization to serve as the PI is at the discretion of individual departments or colleges. Some may require the Faculty Mentor be named the PI while others allow the student to be named the PI.

Please make special note that under the definitions provided in 45 CFR 46.102(l) the following activities (including but not limited to) are deemed **not** to be research under the purview of Human Subjects’ research regulation, or the IRB:

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.



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3. Training of Student Researchers

Student researchers engaged in human subjects' research must complete the human research education training required for all research team members as outlined in the Drexel HRP SOP for Investigator Responsibilities. Instructors should actively instruct the students in the application of ethical principles and regulations as they apply to the class project, including, but not limited to: respect for persons as it translates into informed consent, courtesy, avoidance of unnecessary discomfort, and protection of privacy.

All submissions to the Drexel University IRB with a student named as the Principal Investigator require a Drexel University faculty mentor to be identified as outlined in Drexel HRP SOP for Investigator Responsibilities and ORI-002 Principal Investigator Eligibility and Responsibilities. Students and mentors should contact the IRB Office with any questions.

4. Student and Course Projects, Not Human Subjects Research

Class projects are generally conducted for educational purposes and are not designed to develop or add to generalizable knowledge. Learning how to conduct ethical research is an important part of a student's educational experience. To receive a formal, written determination from the Drexel University IRB that a class project is not human subjects research, investigators must submit to the IRB.

Instructors and departments are encouraged to contact the IRB for guidance about ways to handle topics such as privacy, confidentiality, informed consent for participation, and professional ethics when class projects are part of the course syllabus. These issues may remain even when IRB approval is not required, in which case instructors, mentors, departments, and schools play an even greater role in providing the appropriate guidance and oversight.

When student or course projects do not qualify as *Human Subjects Research* under 45 CFR 46.102(l), the IRB recommends the following parameters as best practices for student projects:

- Results of the project are used only by the course instructor for teaching purposes and discussed within the classroom for teaching and learning purposes;
- Activities present no more than minimal risk to participants;
- Vulnerable populations are not targeted (e.g., children under age 18, prisoners, persons who are cognitively impaired, etc.);
- Data collected are recorded in such a manner that the subjects are not identifiable (does not include images in videotapes and photographs which are inherently identifiable); and
- When appropriate, there is a process in place for participants to be informed about and consider participation in the project

5. Responsibility of the Course Instructor

The course instructor is responsible for communicating to the students the ethics of human subjects research, ensuring the protection of human subjects (including a process is in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students' progress.

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When designing a project, students should be instructed on the ethical conduct of research and on how to complete an IRB application when one is required. In particular, instructors and students should:

- Understand the elements of informed consent;
- Understand how to develop appropriate consent documents;
- Plan appropriate strategies for recruiting participants;
- Identify and minimize potential risks to participants;
- Assess the risk-benefit ratio for the project;
- Establish and maintain strict guidelines for protecting privacy and confidentiality, and
- Allow sufficient time for IRB review process (if necessary) and completion of the project.

When considering whether or not a class research project requires IRB review, the instructor or student, as applicable, is encouraged to contact the IRB office for assistance. Please clearly describe the project timeline as student research is often conducted within a limited timeframe.

6. Responsibilities

6.1 Office for Research & Innovation and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining these procedures, applicable tools, training, and monitoring. The HRP Office is responsible for human subject research determinations. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

6.2 Student Researcher Responsibilities

The student researcher is responsible for following these procedures with respect to human research projects and ensuring appropriate submissions. If the student researcher is also the designated Principal Investigator of the project, the student and faculty mentor will share the responsibilities as described in Section 6.3.

6.3 Principal Investigator and Faculty Mentor Responsibilities

The Principal Investigator (and Faculty Mentor as applicable) is ultimately responsible for the conduct and oversight of the project. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following these procedures, ensuring appropriate submissions, approvals and oversight, and submitting the applicable documentation or exceptions to the HRPP/IRB.

7. Resources

- [ORI-002 Principal Investigator Eligibility and Responsibilities](#)
- [ORI-004 Drexel Research Agent Eligibility and Responsibilities](#)



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8. Revision and Workgroup Members

8.1 Revision

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