

The Protection of Human Subjects in Student Projects

Many courses at St. Olaf College provide students with opportunities to carry out inquiry projects involving human subjects. Student human subjects projects vary greatly; they may be informal or rigorous, narrow or far-reaching, qualitative or quantitative, short-term or longer-term. Irrespective of project specifics, when students involve human subjects in their academic work, they incur special obligations to the people they are studying. So, too, do their instructors, their departments, and the College-wide Institutional Review Board (IRB).¹ The purpose of this document is to describe the major types of student projects, the oversight authority for different project types, and the complementary roles of instructors, departments or programs, and the college-wide IRB in safeguarding the rights and well-being of human subjects in student projects.

I. MAJOR TYPES OF STUDENT PROJECTS INVOLVING HUMAN SUBJECTS

Student human subjects projects can be categorized in relation to the federal criteria for the exercise of IRB authority. According to federal regulations,² an institution's IRB has jurisdiction over a project when all three of the following criteria are met:

Criterion 1: *The project will be conducted at and/or sponsored by the institution.*

Criterion 2: *The project involves the collection of data through intervention or interaction with human subjects and/or the collection or analysis of identifiable private information.*

Criterion 3: *The project is a systematic investigation intended to develop or contribute to generalizable knowledge.*³

Virtually all student projects at St. Olaf are conducted at or sponsored by the College, and therefore meet Criterion 1.⁴ Many student projects at St. Olaf, particularly in some social and natural science courses, also meet Criterion 2, because they involve surveys, interviews, experiments, observations, or some other form of interactive data collection. However, very few student projects meet Criterion 3, even though they may be designated as “research projects” in syllabi or assignments. This is because the principal purpose of most student projects is not to contribute to the knowledge of others in a disciplinary or interdisciplinary

¹ See *The St. Olaf College Institutional Review Board: Mission and Responsibilities* for a description of the purpose and role of the College IRB with respect to all projects with human subjects.

² In general, “federal regulations” in this document refers to *The Code of Federal Regulations*, Title 45, Part 46, “Protection of Human Subjects,” often referred to as “the Common Rule.”

³ All of these criteria and the federal regulations supporting them are described in more detail in the human subjects protection policy document, *Jurisdiction of the St. Olaf College Institutional Review Board (IRB)*.

⁴ Some student projects are not considered to be “sponsored by” the college, such as projects undertaken by St. Olaf students participating in an off-campus program not led or taught by St. Olaf faculty, or projects undertaken by St. Olaf students during a summer internship for which they are not receiving credit. In those cases, the host institutions are responsible for ensuring the ethical conduct of student projects, as part of the educational services they are providing the students.

field, but rather *to develop the knowledge or understanding of the student investigators themselves*. In other words, most student projects are primarily *pedagogical* rather than scholarly; they are unlikely to constitute contributions to generalizable knowledge. This does not mean that pedagogical projects are without intellectual merit. Nor does it mean that the student investigators are under no obligation to treat human subjects ethically. It simply means that they have a different purpose, and are therefore monitored differently, than federally-defined “research” projects.

This distinction between pedagogical and research purposes suggests the following typology of student projects involving human subjects:

A. *Pedagogical projects*

1. *Limited-inquiry projects*. Some pedagogical projects gather information from and/or about people *to enrich student learning of specific course topics*. Students may conduct interviews or surveys, observe physical characteristics or behavior, or gather information about human subjects in some other way to elaborate on course readings, inform a class discussion, support a graded assignment, etc. Formal principles of research design are often relaxed for these kinds of projects. Project findings may be shared with the subjects, but they are not portrayed as “research results” or generalized to any population other than the study population from which the sample was selected.
2. *Research practica*. The principal purpose of research practica is *to provide instruction and experience in disciplinary research*. Research practica familiarize students with standard methodological principles of social or natural science research by giving them opportunities to apply these principles in projects of their own design. Projects of this type are typically, though not exclusively, conducted in disciplinary research methods or practicum courses. As with limited-inquiry projects, findings from research practica may be shared with the subjects or other related audiences, but they are not portrayed as “research results” or generalized to any population other than the study population from which the sample was selected.

B. *Generalizable research projects*

Generalizable research projects, for purposes of ethics review, are student projects that meet all three criteria embedded in the federal definition of research within IRB jurisdiction. Like pedagogical projects, they are sponsored by the College and they involve interaction, intervention, and/or personally-identifiable private data. However, unlike pedagogical projects, their principal purpose is to develop or contribute to “generalizable knowledge.” Because “generalizable knowledge” implies a rigorous and replicable research design, most students undertaking a generalizable research project will already have completed at least one course in disciplinary research methods. Furthermore, similar to projects within IRB jurisdiction undertaken by St. Olaf employees, most generalizable research projects undertaken by students will include a specific plan for dissemination beyond the St. Olaf community. Such projects are most

likely to be initiated in an independent study or research course or in a senior capstone course.

II. OVERSIGHT OF STUDENT HUMAN SUBJECTS PROJECTS

The *St. Olaf Code of Ethics for Projects with Human Subjects* applies to *all* types of student projects, whether of the pedagogical or research variety. All student projects should comply with the ethical principles incorporated in the *Code*, and all should be reviewed for compliance with the *Code* before data collection begins, with the initial review to be conducted by the instructor.

Some student projects need no additional review beyond that provided by the instructor. However, other projects require more elaborate review, depending on the specific characteristics of a given project. Most of these require formal review and approval by one or two members of a Faculty-specific intermediate human subjects review committee; some require joint review by one or more intermediate-level reviewers and one or two members of the college-wide IRB; and a few projects require federally-regulated review and approval by one or more members of the college-wide IRB. A detailed description of the different types of projects, the different characteristics projects may have, and the specific review procedures required for different kinds of projects, is provided in a separate document, “*Who Needs to Review My Project? Determining the Appropriate Review Procedure for a Human Subjects Project.*”

III. THE RESPONSIBILITIES OF INSTRUCTORS, DEPARTMENTS, AND THE COLLEGE-WIDE IRB

A. Instructor responsibilities

Instructors have a critical and multifaceted role to play in safeguarding the rights and well-being of human subjects in student projects. Their responsibilities include the following:

- (1) Familiarizing themselves with the research ethics code(s) of their own discipline(s) and with the College’s *Code of Ethics for Projects with Human Subjects*;
- (2) Designing assignments and instructions that are informed by, and/or introduce, the research ethics of their own discipline(s) and relevant sections of the *Code*;
- (3) Categorizing student project proposals accurately so they are reviewed by the appropriate entities (see “*Who Needs to Review My Project?*”);
- (4) Providing students with any additional tools and resources they need to prepare informed and thoughtful applications for review;

- (5) Reviewing all student projects in their courses (including those that are also subject to review at the intermediate or IRB level) to ensure that project proposals are consistent with the requirements of the *Code* before data collection begins;
- (6) For projects requiring additional review, helping students to adjust their review applications to meet the requirements of the *Code* before an application is submitted to the next level of review;
- (7) If necessary, helping students adjust their applications again in response to feedback from intermediate or IRB reviewers;
- (8) Monitoring the conduct of approved projects to ensure that they are carried out as specified in the final application;
- (9) Consulting at any time with the appropriate intermediate-level Human Subjects Review Committee and/or the college-wide IRB to support their instructional work with students;
- (10) Providing feedback to the intermediate-level Human Subjects Review Committee and/or the college-wide IRB to improve college policies and procedures for the protection of human subjects.

B. Departmental responsibilities

Departments also have a critical role to play in preparing and supporting the instructional work of faculty whose students undertake projects involving human subjects. Their responsibilities include the following:

- (1) Orienting instructors to departmental and college-wide policies, procedures, and resources for the ethical conduct of student projects involving human subjects;
- (2) Supporting instructors seeking faculty development in research ethics;
- (3) Recruiting departmental faculty to serve on an intermediate-level Human Subjects Review Committee;
- (4) Promoting collaboration between the department, the intermediate-level Human Subjects Review Committee, and the college-wide IRB.

C. IRB responsibilities

The IRB is responsible for supporting departments and instructors in their efforts to protect human subjects in student projects and to educate students about the rights and well-being of human subjects. In particular, the IRB's responsibilities with respect to student projects include:

- (1) *Educating St. Olaf faculty* about the ethical and legal obligations associated with human subjects projects;

- (2) *Conducting reviews of student generalizable research projects* to ensure that such research will be carried out in a manner which safeguards the rights and well-being of the subjects;
- (3) *Collaborating with each Faculty's intermediate-level Human Subjects Review Committee* to support the instructional and scholarly work of individual faculty members and to assure compliance with federal and college policy.

Instructors are encouraged to consult at any time with any member of the college-wide IRB or with the chair of the intermediate-level Human Subjects Review Committee appropriate to their Faculty for advice and assistance on the protection of human subjects in student projects. Additional resources and contact information are available on the IRB website:

<http://www.stolaf.edu/academics/irb/>