

## **Jurisdiction of the St. Olaf College Institutional Review Board (IRB)**

According to federal regulations<sup>1</sup> and College policy,<sup>2</sup> all College-sponsored projects involving federally-defined “research with human subjects” are within the jurisdiction of the St. Olaf College Institutional Review Board (IRB), irrespective of whether or how a given project is funded. This means that the IRB is responsible for safeguarding the rights and well-being of the subjects in all such projects, although the IRB exercises this responsibility in different ways for projects with different characteristics and involving different kinds of research procedures.

According to federal regulations, a project is defined as “research” that falls within the jurisdiction of an institution’s IRB when the project meets all three of the following criteria:

**Criterion 1:** *The project will be conducted at or sponsored by the institution.*<sup>3</sup>

**Criterion 2:** *The project involves the collection of data through intervention or interaction with human subjects and/or the collection or analysis of personally-identifiable private information.*<sup>4</sup>

**Criterion 3:** *The project is a systematic investigation designed to develop or contribute to generalizable knowledge.*<sup>5</sup>

Below is a discussion of the way St. Olaf College interprets each of these criteria.



**Criterion 1:** *The project will be conducted at or sponsored by St. Olaf College.*

Projects conducted at or sponsored by St. Olaf College may include one or more of the following:

- Projects conducted by or under the direction of a St. Olaf employee in connection with his or her institutional roles and/or responsibilities (e.g., in support of his or her instructional, scholarly, administrative, or governance work);
- Projects conducted by or under the direction of a St. Olaf employee who makes substantial use of any St. Olaf property, equipment, or facility;

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<sup>1</sup> 45 CFR 46.101; see also U.S. Department of Health and Human Services Office of Human Research Protections (OHRP), *IRB Guidebook*, ch. 1, p. 2.

<sup>2</sup> The Federalwide Assurance provided by St. Olaf College to the federal government (FWA00004715, approved by the U.S. Department of Health and Human Services Office of Human Research Protections, May 16, 2003) indicates that the College elects to apply the federal Common Rule for the protection of human subjects to *all* College-sponsored research with human subjects, irrespective of whether a given project is federally-funded.

<sup>3</sup> 45 CFR 46.103(b)(1).

<sup>4</sup> 45 CFR 46.102(f)

<sup>5</sup> 45 CFR 46.102(d)

- Projects conducted by or under the direction of a St. Olaf employee which involves the participation of St. Olaf students, faculty, staff, alumni, Board members, and/or administrators;
- Projects involving the use of the institution's non-public information to identify or contact prospective subjects;<sup>6</sup>
- Projects involving the analysis of the institution's non-public information.<sup>7</sup>

When a project is being conducted at St. Olaf College by an investigator who is not affiliated with the college, approval by the St. Olaf IRB may be required prior to the commencement of the project, even if the project has already been approved by another institution's or organization's IRB.

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

**(1) Intervention or interaction** with a human subject may occur face-to-face, on paper, electronically, or by telephone. Data collection methods involving such interventions or interactions include, but are not limited to:

- Written surveys
- Oral interviews
- Focus groups
- Experiments
- Written or physical tests
- Participant-observation
- Behavioral coding
- Measurement of physical characteristics (heart rate, height, weight, etc.)
- Collection of physical samples (blood, saliva, hair, etc.)

**(2) Personally-identifiable private information** is defined as follows:

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<sup>6</sup> Such research may be conducted by guest investigators not affiliated with St. Olaf College, such as visitors to the campus or off-campus scholars engaged in human subjects research on campus. These guest investigators must arrange for St. Olaf IRB review of proposed projects through a St. Olaf employee who agrees to serve as the project liaison. The liaison should: (1) provide the guest investigator with the appropriate institutional forms and policies and (2) assist the guest investigator with the preparation of the application for review to the St. Olaf IRB. **Note: A separate policy document governing research by non-affiliated investigators will eventually be developed.**

<sup>7</sup> See Note 6.

- “*Identifiable*”: “[T]he identity of the subject is or may readily be ascertained by the investigator or associated with the information” by the investigator or readers of the investigator’s work, even if the data are made anonymous in collection or reporting (45 CFR 46.102 (f)).
- “*Private information*”: “Private information includes 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 which the individual can reasonably expect will not be made public (for example, a medical record).” (45 CFR 46.102 (f))

Data collection methods that may yield personally-identifiable private information include, but are not limited to, the following:

- Unobtrusive observation (with or without video- or audio-taping)
- Analysis of existing data, documents, or specimens (including, but not limited to, transcripts, medical records, artifacts, applications, etc.) that include personally-identifiable private information and/or that include identifying information that would permit the researcher, or readers of the researcher’s work, to link individual subjects to the data (whether the data is reported in individual or aggregate form).

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

(1) Systematic investigations that may yield **generalizable knowledge** may use any of the data collection methods described above. Such investigations include, but are not limited to, the following kinds of projects:

- Hypothesis-testing
- Case studies
- Pilot projects (e.g., preliminary administration of questionnaires or interview protocols for purposes of instrument improvement)
- Ethnographies
- Program evaluations
- Demonstration projects
- Archival projects

(2) Projects are defined as “**designed to develop or contribute to generalizable knowledge**” when they include **both** of the following characteristics:

- **The project design and/or results are intended to be generalizable.** Indicators of intent to generalize include, but are not limited to, the following:
  - The project investigator identifies the project design as replicable

- The project investigator identifies the project results as intended to contribute to generalizable knowledge
  - The project investigator states an intent to generalize or apply the findings to a population other than, or in addition to, the study population from which a sample was drawn
  - The project investigator specifies a larger population(s) to which the findings will be generalized or applied
- **The researcher intends, or may reasonably anticipate, dissemination of project results to an audience outside the College.** Potential means of dissemination include, but are not limited to:
    - Articles, books, and monographs in professional, peer-reviewed scholarly venues, both paper and electronic
    - Presentations to conferences or annual meetings of professional associations
    - Websites
    - Reports, exhibits, or presentations for public or private institutions (government agencies, not-for-profit institutions, companies, etc.)
    - Exhibits or presentations for members of the general public

**Note:** Many projects characterized by their investigators as “research projects” do not meet Criterion 3 for federally-defined research within the jurisdiction of an IRB. In other words, a project may constitute a “systematic investigation” without necessarily contributing to “generalizable knowledge.” Examples include:

- Evaluation forms completed by participants in college-sponsored programs or by clients of college services, where findings may be generalized to the study population (all participants in the program being evaluated, or all clients of the service being evaluated) but not to any other population.
- Surveys, interviews, observations, oral histories, etc. where the intent is to draw conclusions about the subjects alone, not to draw conclusions about any larger population. These are most commonly conducted in pedagogical or administrative projects.
- Student research practica, where the principal purpose is to provide students opportunities to develop and practice research skills rather than to develop and disseminate generalizable knowledge. Student research practica are subject to alternative review procedures rather than to college-wide IRB review, although the application form and criteria for review are the same.<sup>8</sup>

Investigators conducting projects which involve human subjects but which do not constitute contributions to “generalizable knowledge” are still obligated to safeguard the

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<sup>8</sup> See additional discussion of the definition and oversight of student research projects in the IRB policy document, *The Protection of Human Subjects in Student Projects*.

rights and well-being of project subjects. Ethical guidelines for all inquiry projects, including those not technically defined as “research” projects within the jurisdiction of the IRB, are provided in the *St. Olaf College Code of Ethics for Projects with Human Subjects*. Many projects still require review and approval by an entity other than the IRB (such as an intermediate-level Human Subjects Review Committee) to ensure appropriate protection of human subjects.