



Research Ethics for Inquiries Involving People: Education, Ethics Planning, and Review Policies

St. Olaf faculty, staff, and students are ever more deeply engaged in inquiry projects that involve gathering information from or about people, and in sharing their findings beyond the college on websites, at conferences, and in community organizations. St. Olaf College maintains a written assurance to the federal government that all of its inquiries involving people will be guided by the three ethical principles of *beneficence*, *respect*, and *justice*. College policies are designed to ensure that these three principles are consistently understood and observed, whatever the particulars of a specific investigation. At the same time, the policies acknowledge that some types of projects require more sophisticated understanding of research ethics, additional steps to protect participants, and additional oversight to ensure that the appropriate steps are being taken.

REQUIREMENTS AND RESOURCES

This section provides basic information about the three major components of the college's research ethics policy:

- **Education** in research ethics for investigators and (for student projects) faculty/staff supervisors, customized to the type of project being undertaken;
- **Ethics planning forms** to ensure that the project design includes appropriate measures to protect the rights and well-being of the people being studied;
- **Review** for some types of projects, with the type of review depending on the features of the project plan.

Subsequent sections describe the different types of inquiry projects and the specific education, ethics planning, and review requirements associated with each.

Education requirements and resources

- [**Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations - Required for all projects.**](#) This is a statement of principles prepared by the St. Olaf IRB that summarizes the basics of research ethics in inquiries involving people. It is organized around the principles of beneficence, respect, and justice, and explains the specific features that investigators usually need to build into their project design to ensure that those principles are honored. All investigators, and all faculty/staff supervisors of student investigators, are asked to read this handout prior to project planning.
- [**CITI online training in research ethics - Required for some projects and recommended or optional for others.**](#) St. Olaf subscribes to the University of Miami's Collaborative Institutional Training Initiative (CITI), which provides on-line mini-courses in research ethics to investigators in thousands of academic institutions, government agencies, and commercial organizations within and beyond the US. Each course consists of a series of topical modules, accompanied by a short quiz at the end of each module. A minimum quiz score of 80% for the course as a whole

(not necessarily each individual module) is required for successful course completion. The following CITI course options have been developed for St. Olaf investigators and supervisors:

- General Social and Behavioral Investigations
- Investigations with Greater than Minimal Risk
- Investigations of Vulnerable Populations
- Investigations Conducted Abroad
- Records-Based and Internet Investigations
- Training for IRB Members

Different courses are appropriate for different types of projects, as described below. The courses also have a number of modules in common, so completing an additional course will require completing only the modules that were not included in prior courses. To assist new CITI trainees in navigating the CITI site and selecting the appropriate courses, the St. Olaf IRB has prepared a detailed guide on [How to Access and Complete Appropriate Training on the CITI Website](#).

Successful completion of the appropriate CITI training is a prerequisite for IRB review of projects requiring an IRB application in addition to an Ethics Plan. It is also a prerequisite for faculty/staff supervisor review of an Ethics Plan in projects where the use of the Ethics Plan form is required. In order to remain current with any changes in federal guidance, renewal of training is required every three years.

Ethics planning forms and requirements

- **[Ethics Plan](#) and [attachments](#) as appropriate to the project – *Recommended for all projects and required for some.* The Ethics Plan and other forms are designed to help investigators know what steps to take in order to design and carry out an ethical inquiry. The Ethics Plan links specific provisions for protecting project participants to the three principles of beneficence, respect, and justice, so new investigators can understand why each provision is necessary. Use of the Ethics Plan is recommended for Type 1 projects and required for Types 2 and 3 projects (described below).**
- **[Request for IRB Advisory Review](#) – *Required periodically for some projects, available for all projects.* Some types of projects that do not require formal IRB review have other project features that pose distinctive ethical issues. In these cases (identified and described below), the IRB provides an advisory review of the project Ethics Plan, principally as a form of supplementary professional development for the investigator and (in the case of student projects) the project supervisor. Faculty/staff investigators and project supervisors are required to submit a Request for IRB Advisory Review when they are undertaking such projects for the first time, and every three years after that. IRB advisory review is also available for any other project at the request of a faculty/staff instructor or supervisor.**
- **[Application for IRB Review](#) – *Required only for selected projects.* Projects that pose risks to participants or that study vulnerable persons (see below) require the completion of an Application for IRB Review in addition to the Ethics Plan and other supplementary forms. The application for IRB review solicits information about the project that is not elicited by the Ethics Plan or related forms.**

- **Modification Proposal for Previously-Approved IRB Application - Required only for selected projects.** A Modification Proposal should be submitted when the investigator wishes to make changes to an inquiry project that has a current IRB approval. Such changes may include the project's duration, participants, recruitment methods, questionnaires, consent process, or other procedures as described in the project IRB Application, Ethics Plan, and/or attachments.
- **Request for Continuing Review of Previously-Approved IRB Application - Required only for selected projects.** Federal regulations require annual review of an IRB-approved inquiry when the data collection component of a project extends beyond one year. A Request for Continuing Review should be submitted three weeks prior to the end date of the previous approval.

Review and approval requirements

- **Review and approval by faculty/staff supervisor – Required for all student projects.** Faculty/staff supervisors review student project plans and accompanying documents in relation to the principles of beneficence, respect, and justice as described in the St. Olaf statement of principles, [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#), and as amplified in the CITI course applicable to the project. If the supervisor or the nature of the project requires the use of the college Ethics Plan, the supervisor may wish to use the college's [Ethics Plan Review form](#), which has been designed specifically to track with the elements of the Ethics Plan itself. For projects requiring only supervisor approval, students may begin contacting prospective participants and gathering data as soon as they have been notified of that approval.
- **Project revision in response to IRB Advisory Review – At the discretion of the faculty/staff investigator or project supervisor.** An IRB Advisory Review of a project Ethics Plan and relevant attachments is just that – advisory. IRB *approval* is required only for projects requiring an IRB application (see below). Once the IRB has provided an advisory review to a faculty/staff investigator or project supervisor, the faculty/staff member determines how best to adjust the project. In the case of student projects, the IRB typically provides a copy of the advisory review to the student investigator as well as to the faculty/staff supervisor, to facilitate collaboration between the student and the supervisor in making final decisions about project provisions. The IRB does not ask to review or approve any revised project plans, though subsequent review can be provided upon request.
- **Review and approval by the St. Olaf IRB – Required for projects subject to IRB review.** When IRB approval is required for a project, the faculty/staff investigator or project supervisor submits the IRB Application, Ethics Plan, and related attachments to the [IRB Administrator](#). One or more members of the IRB will review the documents and communicate the findings to the faculty/staff member. Project revision may be required as a condition of IRB approval. Investigators may begin contacting prospective participants and collecting data as soon as they have been notified of IRB approval.

Different types of projects require different types of education, ethics planning forms, and review procedures. The remainder of this document describes three basic project types and the procedures associated with each. Projects that are supported by federal funding may be subject to additional

requirements; please confer with the [St. Olaf Institutional Review Board chair](#) to determine the appropriate procedures for federally-funded projects.

TYPE 1: WITHIN-THE-COLLEGE NO-RISK PROJECTS

Characteristics of Type 1 projects

Within-the-college no-risk projects have **all** of the following characteristics:

- **The procedures involved in the inquiry do not pose risks to the participants.** An inquiry poses minimal or no risk when the project procedures would not cause participants to experience psychological, social, legal, or physical harm or discomfort beyond what they would be likely to experience in normal daily activities; see the St. Olaf [Ethics Plan](#) form, Item 6, for a detailed list of procedures that may pose risks to participants.
- **The inquiry is not focused on a “vulnerable population.”** Persons who are members of “vulnerable populations” (a term that is used in federal policies for the protection of research participants) may be susceptible to undue influence or coercion, or may experience greater risk as a result of project participation, and therefore require special protections. Examples of “vulnerable populations” include:
 - Minors (children and adolescents under the age of 18)
 - Individuals who may be educationally or economically disadvantaged (e.g., recent immigrants, low-income persons, persons of color)
 - Adults (age 18 or older) whose decision-making may be compromised for reasons of mental illness, developmental disability, age-related dementia, or other condition
 - Individuals in correctional institutions, health care facilities, or long-term care facilities
 - Individuals with physical conditions that may make some types of procedures riskier for them (e.g., pregnant women, persons with food allergies)

A project is considered to be “focused” on the study of a vulnerable population when most or all of the participants are members of one or more of these groups and when the principal purpose of the project is to draw conclusions about that category of persons. If a project includes some “vulnerable” persons simply because they happen to be part of the larger group being studied, but the project is not principally about those persons (e.g., a study about college student behaviors in which some of the sampled students are low-income), then the project is not considered to be focused on a vulnerable population.

- **The people being studied are limited to current St. Olaf students or employees.** An inquiry may be a Type 1 project if the **ONLY** participants are currently-enrolled St. Olaf students or currently-employed faculty or staff.
- **The results of the inquiry are not shared outside the college.** This means that findings are not posted on the college website, distributed to external organizations, presented at conferences, published, or otherwise shared with audiences or individuals external to St. Olaf. Findings that are shared in campus poster sessions or oral presentations with a limited number of non-St. Olaf guests in attendance are still considered “internal,” since the primary audience for these presentations consists almost exclusively of St. Olaf students and employees.

Examples of within-the-college no-risk projects are:

- (1) student interviews with other St. Olaf students for a class project involving questions posing no more than minimal risk, with results to be shared only with the instructor and other students in the class;
- (2) a no-risk survey of St. Olaf staff by a St. Olaf office for internal use.

Education requirements for Type 1 projects

- ***For supervisors of student projects:***
 - ***Required:*** [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#).
 - ***Recommended:*** One of the following [CITI](#) course options, as appropriate to the project being supervised:
 - ✓ ***General Social and Behavioral Investigations***
 - ✓ ***Records-Based and Internet Investigations***

The *General Social and Behavioral Investigations* course addresses the ethical concerns that are likely to arise in most inquiries involving people. However, if students are likely to conduct projects involving the analysis of pre-existing data and/or data available on the internet, it is recommended that the supervisor complete the *Records-Based and Internet Investigations* course, which includes all the modules in the *General* course but also includes additional modules for projects that involve the use of existing and/or internet-based data. Investigators should consult [How to Access and Complete Appropriate Training on the CITI Website](#) for guidance on navigating the CITI training website and selecting the appropriate course(s).

- ***For student, faculty, and staff investigators:***
 - ***Required:*** [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#).
 - ***Optional:*** One of the following [CITI](#) course options, as appropriate to the project being supervised:
 - ✓ ***General Social and Behavioral Investigations***
 - ✓ ***Records-Based and Internet Investigation***

See above for a description of the content of these courses. [CITI training](#) is particularly recommended for investigators whose inquiry involving people is part of a larger learning experience in social research, or who are likely to undertake future inquiries involving people. Investigators should consult [How to Access and Complete Appropriate Training on the CITI Website](#) for guidance on navigating the CITI training website and selecting the appropriate course(s).

Ethics planning forms and review requirements for Type 1 projects

- **For student projects:**

- ***Recommended:* Completion of [Ethics Plan](#) and related forms as appropriate.** While college policy does not require the completion of an Ethics Plan for Type 1 projects, a project supervisor may elect to require the use of this form because of its educational value as well as its benefits for the ethical design of the project.
- ***Required:* Review and approval of project ethics by faculty/staff supervisor.** Whatever the supervisor's requirements for planning and documentation may be, the supervisor should ensure that the ethics provisions of the project (whether recorded on the Ethics Plan form or in some other way) uphold the principles of beneficence, respect, and justice as described in [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#). Supervisors who require students to complete the St. Olaf [Ethics Plan](#) may wish to use the St. Olaf [Ethics Plan Review form](#) to provide feedback and indicate project approval once the investigator has made any needed changes to the plan. In either case, student investigators should not begin their data-collection (including recruitment of prospective participants) until **after** the faculty/staff project supervisor has determined that the investigator has met all education and planning requirements established by the supervisor, including the satisfactory completion of any St. Olaf forms.
- ***Recommended:* Advisory IRB review of Ethics Plan for new project supervisors; no IRB approval required.** Although formal review of ethics plans for within-the-college no-risk projects is not required, first-time supervisors of a student inquiry involving people may find it helpful to require the student to complete a written Ethics Plan, use the St. Olaf [Ethics Plan Review form](#) to prepare feedback for the student, and then seek an advisory review by an IRB member before final project approval. The completed Ethics Plan can be submitted to the [IRB Administrator](#) with a [Request for IRB Advisory Review](#). Faculty and staff supervisors are welcome to contact any [member of the St. Olaf IRB](#) at any time for advice on a student project plan.

- **For faculty and staff projects:**

- ***Recommended:* Completion of [Ethics Plan](#) and related forms as appropriate.** The use of the Ethics Plan form is particularly encouraged for investigators who are new to inquiries involving people.
- ***Recommended:* Advisory IRB review of Ethics Plan for new project investigators; no IRB approval required.** Although formal review of ethics plans for within-the-college no-risk projects is not required, first-time faculty and staff investigators may find it helpful to prepare a written Ethics Plan and seek an advisory review by an IRB member. The completed plan can be submitted to the [IRB Administrator](#) with a [Request for IRB Advisory Review](#). Any investigator conducting a Type 1 project is welcome to consult at any time with any [member of the St. Olaf IRB](#) for advice on project design.

TYPE 2: BEYOND-THE-COLLEGE NO-RISK PROJECTS

Characteristics of Type 2 projects

Beyond-the-college no-risk projects have the following characteristics:

- The procedures involved in the inquiry **do not pose risks** to the participants. See “Characteristics of Type 1 projects” above for details.
- The inquiry is **not focused on a “vulnerable population.”** See “Characteristics of Type 1 projects” above for details.
- **The people being studied include non-St. Olaf individuals** (people who are not current St. Olaf students or employees) – OR – **findings from the inquiry may be disseminated to audiences beyond the college** through postings on publicly-accessible websites, conference or community presentations, publications, or other means. (In some cases an investigator may not know whether findings will be externally disseminated; external dissemination may depend on the nature of the findings, acceptance for publication, or other unknowns. These projects should be treated as Type 2 projects to preserve the option of future dissemination.)

Examples of beyond-the-college no-risk projects are:

- (1) an academic civic engagement course project that includes no-risk interviews with members of a community organization that serves a broad cross-section of Northfield residents
- (2) a department assessment project where findings may be presented at an academic conference.

Education requirements for Type 2 projects

- **For supervisors of student projects:**
 - **Required:** [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations.](#)
 - **Required:** One of the following [CITI](#) course options, as appropriate to the project:
 - ✓ **General Social and Behavioral Investigations**
 - ✓ **Records-Based and Internet Investigations**
 - ✓ **Investigations Conducted Abroad**

As indicated above, the *General Social and Behavioral Investigations* course addresses the ethical concerns that are most likely to arise in most inquiries involving people. The other two courses include all the modules in the *General* course but also include additional modules for projects that involve the analysis of existing and/or internet-based data, or that study people residing outside the US. If a project supervisor will be overseeing more than one of these types of projects, the supervisor should complete all the corresponding courses. The CITI system is set up to recognize modules that have already been completed, so completing an additional course will require completing only the modules that were not included in prior courses. The St. Olaf IRB Administrator can access CITI records to verify course completions by St. Olaf students and employees.

- **For student, faculty, and staff investigators:**
 - **Required:** [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#).
 - **Required:** One or more of the following [CITI](#) course options, as appropriate to the project:
 - ✓ *General Social and Behavioral Investigations*
 - ✓ *Records-Based and Internet Investigations*
 - ✓ *Investigations Conducted Abroad*

See above information concerning these course options.

Ethics planning forms and review requirements for Type 2 projects

- **For student projects:**
 - **Required:** Submission of [Ethics Plan](#), along with related forms as appropriate, to the faculty/staff supervisor. The supplementary forms needed depend on the features of the project. The Ethics Plan form provides guidance concerning appropriate attachments.
 - **Required:** Ethics Plan review and approval by faculty/staff supervisor. The supervisor reviews the Ethics Plan and accompanying documents in relation to the principles of beneficence, respect, and justice as described in [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#) and as amplified in the CITI course(s) applicable to the project. The supervisor may wish to use the St. Olaf [Ethics Plan Review form](#) to provide feedback and indicate project approval once the investigator has made any needed changes to the plan. Students should not begin contacting prospective participants or otherwise gathering data until their plans have been approved by their faculty/staff supervisor. Project supervisors are welcome to contact any member of the [St. Olaf IRB](#) at any time for advice on a student project plan.
 - **Required at least once every three years and available any time upon request:** IRB advisory review of Ethics Plan and related forms. Projects that involve non-St. Olaf participants or dissemination beyond St. Olaf can pose ethical issues that are not raised by within-the-college projects. When a faculty or staff member is supervising a beyond-the-college no-risk project for the first time, he or she must request an advisory review of the project after he or she has completed his or her own review and has concluded that the project is “approvable.” The supervisor should submit the student’s Ethics Plan and all attachments, together with a [Request for IRB Advisory Review](#), to the [St. Olaf IRB Administrator](#). A member of the IRB will review the documents and provide feedback to the supervisor with any recommendations for additional changes to project plans before the data collection begins. The supervisor is responsible for overseeing the final design and implementation of the project. The advisory review process should be repeated every three years, which will enable the faculty/staff member to remain current with any changes in federal guidance or college policy. This includes renewing CITI training, as noted above. IRB advisory review is also available for any other project at the request of a faculty/staff supervisor.

- **Available upon request: Certification of IRB Advisory Review.** A statement of certification may be desirable if the student investigator hopes to disseminate findings at a research conference or in a publication. Project supervisors may request certification on the [Request for IRB Advisory Review](#) form.
- ***For faculty/staff projects:***
 - **Recommended: Completion of Ethics Plan, along with related forms as appropriate.** The inclusion of non-St. Olaf individuals as project participants, or the sharing of project findings with audiences outside St. Olaf, increases the obligation of the college to ensure that participants and their information are appropriately protected. The completion of a written ethics plan and accompanying documents will help the college meet this obligation. It will also assist investigators in case their plans change and they decide to share project findings with audiences outside St. Olaf. In most cases, IRB review of Ethics Plans for Type 2 projects will not be required (see below); instead, the completed ethics plans alone will serve as sufficient documentation, since it is keyed to the ethical principles that the college has committed to uphold.
 - **Required at least once every three years and available any time upon request: IRB advisory review of Ethics Plan and related forms.** Projects that involve non-St. Olaf participants or dissemination beyond St. Olaf can pose ethical issues that are not raised by within-the-college projects. When a faculty or staff member is conducting a beyond-the-college no-risk project for the first time, he or she will receive an advisory review of the project by a member of the IRB. The investigator should submit the completed Ethics Plan and all attachments, together with a [Request for IRB Advisory Review](#), to the [IRB Administrator](#). A member of the IRB will review the documents and provide any recommendations for additional changes to project plans before the data collection begins. The investigator is responsible for considering the IRB's feedback in the final design and implementation of the project. Three years after the initial advisory review, the faculty/staff investigator should request another advisory review, which will enable the faculty/staff member to remain current with any changes in federal guidance or college policy. This includes renewing CITI training, as noted above. IRB advisory review is also available for any other project at the request of an investigator.
 - **Available upon request: Certification of IRB Advisory Review.** A statement of certification may be useful if an investigator is seeking grant support, aspires to broader dissemination of the project, or is part of an inter-institutional team where IRB review and approval is required by one or more of the other participating institutions. Investigators may select this option on the [Request for IRB Advisory Review](#) form.

TYPE 3: PROJECTS INVOLVING RISK OR FOCUSED ON THE STUDY OF A VULNERABLE POPULATION

Characteristics of Type 3 projects

Type 3 projects have **either or both** of the following characteristics:

- ***Project procedures pose some kind of risk for the people being studied.*** This includes projects that may cause the people being studied to incur psychological, social, legal, or physical harm or discomfort that exceed what they would encounter in normal daily activities. See the St. Olaf [Ethics Plan](#) form, Item 6, for a detailed list of procedures that may pose risks to participants.
- ***The project is focused on the study of a “vulnerable population.”*** See “Characteristics of Type 1 projects” above for a detailed description of vulnerable populations and the nature of projects focused on the study of such populations.

Projects that involve risk and/or the study of a vulnerable population may or may not involve non-St. Olaf participants, and may or may not include dissemination beyond the college. The education, planning, and review procedures for these projects are determined by the fact that they involve risk or study vulnerable subjects, not by whether the participants or the dissemination are internal or external.

Examples of projects involving risk or the study of vulnerable subjects are:

- (1) interviews with people that include questions about upsetting experiences or illegal activities;
- (2) a survey of high school students.

Education requirements for Type 3 projects

- ***For supervisors of student projects:***
 - ***Required:*** [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#).
 - ***Required:*** One or more of the following [CITI](#) course options, as appropriate to the project being supervised:
 - ✓ ***Investigations with Greater than Minimal Risk***
 - ✓ ***Investigations of Vulnerable Populations***
 - ✓ ***Investigations Conducted Abroad***
 - ✓ ***Records-Based and Internet Investigations***

All of the course options listed above include a common set of core modules and additional modules specific to the type of project being undertaken. Some projects may require completion of more than one course. For example, a project that involves interviews with low-income clients of a social service agency in India would require completion of both the *Investigations of Vulnerable Populations* course and the *Investigations Conducted Abroad* course. If a project requires completion of more than one course, the CITI system will recognize modules that have already been completed, so completing an additional course will require completing only the modules that were not included in prior courses.

The St. Olaf IRB Administrator can access CITI records to verify course completions by St. Olaf students and employees, and successful completion of the appropriate course(s) by the supervisor is a prerequisite for IRB review, which is required for all Type 3 projects.

- **For student, faculty, and staff investigators:**
 - **Required:** [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#).
 - **Required:** One or more of the following [CITI](#) course options, as appropriate to the project being supervised:
 - ✓ *Investigations with Greater than Minimal Risk*
 - ✓ *Investigations of Vulnerable Populations*
 - ✓ *Investigations Conducted Abroad*
 - ✓ *Records-Based and Internet Investigations*

See above information concerning these course options. Successful completion of the appropriate course(s) by the investigator (required minimum course score of 80%) is a prerequisite for IRB review, which is required for all Type 3 projects.

Ethics planning forms and review requirements for Type 3 projects

- **For student projects:**
 - **Required:** Completion of an [Ethics Plan](#), along with related forms as appropriate. The supplementary forms needed depend on the features of the project. The Ethics Plan form provides guidance concerning appropriate attachments.
 - **Required:** Completion of an [Application for IRB review](#). Projects that pose risks to participants or that study vulnerable persons (see below) require the completion of an Application for IRB Review in addition to the Ethics Plan and other supplementary forms. The application for IRB review solicits information about the project that is not elicited by the Ethics Plan or related forms. The application is accompanied by the Ethics Plan and all attachments when it is submitted to the IRB for review (see below).
 - **Required:** **Ethics Plan and IRB Application review and approval by faculty/staff supervisor.** The supervisor reviews the Ethics Plan and accompanying documents in relation to the principles of beneficence, respect, and justice as described in [Inquiries Involving People: Ethical Principles, Practical Applications, and Investigator Obligations](#) and as amplified in the CITI course(s) applicable to the project. The supervisor may wish to use the St. Olaf [Ethics Plan Review form](#) to provide feedback and indicate project approval once the investigator has made any needed changes to the plan. Project supervisors are welcome to contact any member of the [St. Olaf IRB](#) at any time for advice on a student project plan.
 - **Required:** **Ethics Plan and IRB Application review and approval by the St. Olaf IRB.** After the project supervisor has completed his or her own review and has concluded that the project is “approvable,” the supervisor (NOT the student) should submit the student’s Application for IRB review, the Ethics Plan, and all attachments to the St. Olaf [IRB Administrator](#). One or more members of the IRB will review the documents and communicate the findings to the project supervisor. Project revision may be required as a condition of IRB approval. Students should not begin contacting prospective participants or otherwise collecting data until the project supervisor has been notified of IRB approval.

Both the student investigator(s) and the faculty/staff supervisor must have completed the appropriate CITI training in order for the IRB to review the project.

- ***For faculty/staff projects:***

- ***Required: Completion of an [Ethics Plan](#), along with related forms as appropriate.*** The supplementary forms needed depend on the features of the project. The Ethics Plan form provides guidance concerning appropriate attachments.
- ***Required: Completion of an [Application for IRB review](#).*** Projects that pose risks to participants or that study vulnerable persons (see below) require the completion of an Application for IRB Review in addition to the Ethics Plan and other supplementary forms. The application for IRB review solicits information about the project that is not elicited by the Ethics Plan or related forms. The application is accompanied by the Ethics Plan and all attachments when it is submitted to the IRB for review (see below).
- ***Required: Ethics Plan and IRB Application review and approval by the St. Olaf IRB.*** The investigator should submit the Application for IRB review, the Ethics Plan, and all attachments to the St. Olaf [IRB Administrator](#). One or more members of the IRB will review the documents and communicate the findings to the investigator. Project revision may be required as a condition of IRB approval. An investigator should not begin contacting prospective participants or otherwise collecting data until the he or she has been notified of IRB approval. The investigator must have completed the appropriate CITI training in order for the IRB to review the project.

The information in this policy document pertains to inquiry projects that are not federally-funded. Projects that are supported by federal funding may be subject to additional requirements for education, ethics planning, and review; please confer with the [St. Olaf Institutional Review Board chair](#) to determine the appropriate procedures for federally-funded projects.

Investigators and project supervisors are welcome to confer with any member of the IRB at any stage of project design, preparation of ethics planning forms, or project review.