

WHO NEEDS TO REVIEW MY PROJECT?

Determining the Review Procedure for Projects With Human Subjects

The review procedure for a project with human subjects is determined by the intersection of two project characteristics: (1) the project **type**, and (2) the presence of **special factors** that require additional provisions for safeguarding subjects. Part I of this document defines these characteristics and shows how they determine the appropriate review procedure for a project. Part II provides information specific to projects that constitute federally-defined research (identified as “Type III” projects below) and that require IRB involvement in review. **Please note that all projects in which the principal investigator is a student must first be reviewed and approved by the course instructor or faculty/staff project advisor, even if it requires additional review by an intermediate reviewer or one or more members of the St. Olaf Institutional Review Board (IRB).**

One of the challenges investigators face is that the purpose and prospective audience for a project may change as the project unfolds. The IRB recommends that investigators seek the review procedure that is appropriate to the *highest aspiration* they have for a project. If a project is initially intended for St. Olaf audiences only, but an investigator wishes to provide for the possibility that the data would be used at some point in the future in a publication or presentation to an audience beyond St. Olaf, it is best to seek a higher level of IRB review (though depending on the project, the higher level of review may not require IRB involvement). Faculty and staff are encouraged to consult with the IRB chair for additional guidance in determining the appropriate review procedure for their own projects or for projects conducted by students under their supervision.

I. HOW TO DETERMINE THE APPROPRIATE REVIEW PROCEDURE FOR YOUR PROJECT

The following sequence summarizes the key steps in answering the question, “Who Needs to Review My Project?” The terms (many of which are derived from federal regulations) are explained below.

1. Determine the project type:

- Type I** – Limited inquiry for St. Olaf audiences
- Type II** – Limited inquiry for audiences beyond St. Olaf
- Type III-1** – Federally-defined research identified as “exempt”
- Type III-2** – Federally-defined research identified as “expedited”
- Type III-3** – All other federally-defined research

2. Determine whether the project involves special factors:

- Factor A: People** – Study of vulnerable subjects is a principal purpose of the project
- Factor B: Procedures** – Project procedures pose greater than minimal risk to subjects
- Factor C: Privacy** – Identifying information about the subjects is recorded by the investigator

3. Determine the required reviewer(s):

- Basic review** (*self- or instructor-review*) – Type I with no Factors
- Intermediate review** (*review by additional non-IRB faculty/staff member*) – Type I with one or more Factors; Type II with no Factors
- Single-member IRB review** – Type II with one or more Factors; Type III-1; Type III-2
- Full IRB review** – Type III

1. Determine the *project type*

Type I: Limited inquiry for St. Olaf audiences

- The main purpose of the project is to advance the knowledge and understanding of the investigator and other members of the St. Olaf community.
- The project is not designed primarily to yield generalizable knowledge; findings are most appropriately used to draw conclusions only about those who were eligible to participate in the study.
- The primary audience for project findings is the St. Olaf community.

Type II: Limited inquiry for audiences beyond St. Olaf

- The main purpose of the project is to advance the knowledge and understanding of the investigator, other members of the St. Olaf community, and selected audiences beyond St. Olaf as specified in the application for review.
- The project is not designed primarily to yield generalizable knowledge; findings are most appropriately used to draw conclusions only about those who were eligible to participate in the study.
- The primary audience for project findings includes individuals or organizations beyond the St. Olaf community.

Type III: Federally-defined research for scholarly audiences

- The main purpose of the project is twofold: to advance the investigator's knowledge and understanding, and to develop or contribute to generalizable knowledge.
- The project is a systematic investigation, rigorously designed to yield generalizable knowledge; findings are appropriately used to draw conclusions about populations beyond those who were eligible to participate in the study.
- The primary audience for project methods and findings includes professional scholars and researchers.
- Some types of federally-defined research projects are identified in the federal regulations as "exempt" (Type III-1) or "expedited" (Type III-2); see Section II below for details

2. Determine whether the project is characterized by any *special factors* that may require additional safeguards to protect subjects. The completed application form provides the information needed to make this determination.

Factor A (People): Vulnerable subjects

- A project is characterized by Factor A when principal purpose of the project is to study federally-defined vulnerable subjects (e.g., children, economically or educationally disadvantaged persons, residents of health care or long-term care facilities, prisoners). (*Application Item 1-1b*) [45 CFR 46.111 (a) (3)]

Factor B (Procedures): Greater than minimal risk

- A project is characterized by Factor B when project procedures pose greater than minimal risk (i.e., the risk of psychological, legal, economic, academic, professional social, and/or physical harm is greater than would be encountered in normal daily life). (*Application Item 1-4*) [45 CFR 46.111 (a) (1) and (2)]

Factor C (Privacy): Identifying information

- A project is characterized by Factor C when the information recorded about individual subjects includes identifiers, such as names, student ID numbers, social security numbers, etc. (*Application Item 3-2*) [45 CFR 46.101 (b)(2) and (4); 45 CFR 46.111 (a) (7)]

3. Determine the required reviewer(s)**Basic review: Self-review (faculty/staff projects) or instructor/project advisor review (student projects)**

- Type I projects with NEITHER Factor A, B, nor C

Intermediate review: Review by an additional intermediate (non-IRB) reviewer AFTER instructor/project advisor review and approval in the case of student projects

- Type I projects with ONE OR MORE of Factors A, B, or C.
- Type II projects with NEITHER Factor A, B, nor C.

Single-member IRB review: Review by one member of the IRB AFTER instructor/project advisor review and approval in the case of student projects

- Type II projects with ONE OR MORE of Factors A, B, or C
- Type III-1 (“Exempt”) projects (see Part II below)
- Type III-2 (“Expedited”) projects (see Part II below)

Full IRB review: Review by the entire IRB membership AFTER instructor/project advisor review and approval in the case of student projects

- Type III-3 (“Full”) projects (neither Exempt nor Expedited; see Part II below)

II. CATEGORIES OF TYPE III FEDERALLY-DEFINED RESEARCH PROJECTS

Federal regulations establish three different categories of Type III research projects in relation to IRB jurisdiction and review procedures: “Exempt,” “Expedited review,” and “Full review” projects. Below is a description of each category of research, adapted from federal regulations at 45 CFR 46, and its associated St. Olaf review procedure.

Type III-1: Projects eligible for Exempt status**Review procedure: One-time single-member IRB review**

Type III-1 projects eligible for Exempt status consist of one or more of the following kinds of projects [45 CFR 46.101(b)]:

- (1) **Educational research:** Research involving normal educational practices conducted in established educational settings (e.g., courses, programs, schools or colleges as a whole).
Examples: Scholarship of teaching and learning (SoTL) projects; assessment projects in which results will be shared with external audiences of researchers or practitioners; evaluation of grant-funded projects to improve curriculum or instruction
- (2) **Collection of anonymized data through surveys, interviews, oral histories, focus groups, behavioral observations, or tests:** Research involving survey procedures, interview or oral

history procedures, observations of public behavior, or cognitive, diagnostic, aptitude, or achievement tests in which identifying information about the subjects is not recorded.

Examples: Surveys in which subjects provide their information anonymously; interviews or observations in which the investigator does not record names, ID numbers, or any other identifying information

- (3) **Analysis of anonymized or publicly-available existing data:** Research involving the collection or study of existing data, documents, records, or specimens, if identifying information about the subjects is not recorded or if the data sources are publicly available.
Examples: Analysis of student transcripts in which no identifying information (student names, St. Olaf ID numbers, social security numbers, etc.) is recorded by the investigator; collection of data from government websites.
- (4) **Collection of data from public officials or candidates:** Research involving surveys, interviews, behavioral observations or tests in which the subjects are elected or appointed public officials or candidates for public office.
Examples: Interviews with state agency heads; observations of candidate speeches
- (5) **Program evaluation for public agencies:** Research and demonstration projects subject to the approval of governmental agency heads, designed to study or evaluate public benefit or service programs.
Examples: Scholarly research under contract with a government agency
- (6) **Consumer studies with safe foods or flavors:** Taste and food quality studies involving wholesome foods without additives or ingredients above the level determined to be safe by an appropriate federal agency
Examples: Taste tests with safe foods

“Exempt status” does not mean that the project is exempt from the *St. Olaf Code of Ethics for Projects with Human Subjects* or that it is exempt from IRB review. Rather, “exempt status” means that the project is exempt from “*continuing review*” – that is, subsequent reviews of projects that last more than a year (IRB approval must be renewed every twelve months for “expedited review” and “full review” projects). The purpose of the one-time single-member IRB review for Type III-1 projects is to verify that:

- (1) The project is consistent with *St. Olaf Code of Ethics for Projects with Human Subjects*;
- (2) The project falls within one of the above categories and is therefore exempt from continuing review, unless project characteristics change in such a way as to make it no longer exempt.

Type III-2: Projects eligible for Expedited review

Review procedure: IRB single-member review, subject to continuing review provisions

Type III-2 projects eligible for Expedited review have the following characteristics:

- They are characterized by neither Factor A nor Factor B.
- They are not eligible for Exempt status.

- They consist of one or more of the following kinds of projects [45 CFR 46.110; OHRP “Guidance on the Use of Expedited Review Procedures” 08-11-03; OHRP “Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure” 11-09-98]
 - (1) **Research involving a St. Olaf co-investigator that has already been approved by another institution’s federally-registered IRB**
Examples: A project in which a St. Olaf faculty member is a co-investigator but the principal investigator is a faculty member at another institution of higher education and that institution’s IRB has already given approval; a project involving research in a hospital for which the hospital’s IRB has already given approval
 - (2) **Continuing review of research which has previously been approved by the St. Olaf IRB under expedited or full review procedures**
Examples: Evaluation of grant-funded activities in a three-year grant project
 - (3) **Collection of identifiable data through surveys, interviews, oral histories, focus groups, behavioral observations, or tests:** Research involving survey procedures, interview procedures, observations of public behavior, or cognitive, diagnostic, aptitude, or achievement tests, in which identifying information about the subjects **is** recorded.
Examples: Surveys in which subjects provide identifying information and the identifiers are linked to each subject’s information in the data file; interviews or observations in which the investigator records names, ID numbers, or other identifying information, or assigns identifiers and maintains a separate record linking those identifiers to names, ID numbers, or other identifying information
 - (4) **Analysis of identifiable existing data:** Research involving the collection or study of existing data, documents, records, or specimens, in which identifying information about the subjects **is** recorded.
Example: Analysis of hospital records in which identifying information (patient name, case file number, social security number, etc.) is recorded by the investigator
 - (5) **Data collection from voice, video, digital, or image recordings made for research purposes**
Example: Coding of behavior from a video recording of a social event
 - (6) **Collection of biological specimens for research purposes by non-invasive means**
Examples: Small clippings of hair or nails; collection of sweat or saliva
 - (7) **Selected types of blood sample collection**
Examples: Collection by finger, heel, or ear stick or by venipuncture
 - (8) **Selected types of clinical data collection through non-invasive procedures**
Examples: Applying physical sensors to the surface of the body that do not put significant amounts of energy into the subject; moderate muscular strength testing
 - (9) **Selected types of clinical studies of drugs and medical devices**
Examples: See federal regulations cited above

Type III-3: All other federally-defined research projects***Review procedure: Full IRB review***

Type III-3 projects requiring review by the full IRB membership have the following characteristics:

- They are not eligible for either Exempt status or Expedited review.
- Typically, they are characterized by one or more Factors.