

The St. Olaf College Code of Ethics for Projects with Human Subjects Summary of Contents

The *St. Olaf College Code of Ethics for Projects with Human Subjects* (hereafter “the *Code*”) is based upon, and consistent with, the federal Common Rule for the Protection of Human Subjects at 45 CFR 46. The requirements of the *Code*, as well as the requirements of the Common Rule upon which it is based, show what investigators must do to safeguard the rights and well-being of human subjects in projects conducted at or sponsored by St. Olaf College. The College has elected to apply the principles of the *Code* to **all** projects with human subjects, although there are different review procedures for different kinds of projects (see “*Who Needs to Review My Project?*”).

REQUIREMENT 1: APPROPRIATE RISK/BENEFIT RATIO

Anticipated risks to the subjects must be minimized and reasonable in relation to anticipated project benefits [45 CFR 46.111 (a) (1), (2) and (6)].

Concerns:

1. Project costs (time, energy, inconvenience)
2. Different kinds of project risks (psychological, social and economic, physical)
3. Different levels of project risk
4. Special risks for vulnerable populations
5. Project benefits
6. Quality of project design

Steps investigators should take:

1. Anticipate risks and benefits accurately
2. Determine whether risks can be further reduced
3. Determine whether costs and risks are justified
4. Make provisions for any special risks posed to vulnerable participants

REQUIREMENT 2: APPROPRIATE PROCEDURES FOR SUBJECT SELECTION

Subject selection must result in a fair distribution of the risks, costs, and benefits of the project [45 CFR 46.111(a)(3) and (b)].

Concerns:

1. Exploitation
2. Exclusion
3. Overprotection

Steps investigators should take:

1. Select subjects so as to match the burdens of participation with project benefits as closely as possible.
2. Avoid unwarranted exclusion of subjects.
3. Avoid overprotection of subjects.

REQUIREMENT 3: APPROPRIATE PROTECTION OF PRIVACY AND CONFIDENTIALITY

Investigators must protect the privacy of the subject and the confidentiality of the subject's data before, during, and after the conduct of the project [45 CFR 46.111(a)(7)].

Concerns:

1. Respecting subjects' privacy
2. Ensuring the confidentiality of the subjects' information

Steps investigators should take:

➤ *To respect privacy:*

1. Secure appropriate authorization for access to institutional records.
2. Consult with institutions about their own privacy protections.

➤ *To maintain confidentiality:*

1. If possible, ask subjects to provide information anonymously.
2. If anonymity is not possible, “anonymize” data as it is gathered.
3. Do not disclose the identities of the subjects who participated in the project without their consent.
4. Do not include personally-identifiable information about individual subjects in project reports without their consent.
5. Keep the subjects’ data physically secure.

REQUIREMENT 4: APPROPRIATE PROVISIONS FOR OBTAINING INFORMED CONSENT

In most cases, investigators must secure the legally effective informed consent of the subject before involving the subject in the project. [45 CFR 64.111 (a) (4) and (5); 45 CFR 46.116; 45 CFR 46.117]

Concerns:

1. Sufficiency of information provided to the subjects
2. Understandability of information provided to the subjects
3. Voluntary nature of any decision to participate
4. Appropriate documentation
5. Preservation of the subjects’ legal rights and recourse
6. Circumstances warranting alteration in informed consent procedures

Steps investigators should take:

1. Determine whether project information should be provided in writing.
2. Provide basic information about the project in an accurate and understandable way (*see checklist for preparing basic project information*).
3. Provide additional information as appropriate to the project (*see checklist of additional information required for some projects*).
4. Provide a written consent form, if appropriate.