

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

### INTRODUCTION

When members of the St. Olaf community undertake projects that involve collecting or analyzing information about people, they incur ethical and, in some cases, legal<sup>1</sup> obligations to protect the rights and well-being of the subjects of their inquiry. The purpose of the *St. Olaf College Code of Ethics for Projects with Human Subjects* (hereafter “the *Code*”) is to describe the steps investigators need to take to meet these obligations. The *Code* is based upon, and consistent with, the federal Common Rule for the Protection of Human Subjects at 45 CFR 46. All human subjects projects at St. Olaf College are to be designed and carried out in a manner consistent with the *Code*, with different individuals or units of the College responsible for overseeing different kinds of projects.<sup>2</sup> The requirements of the *Code* show what investigators must do to ensure the ethical treatment of human subjects in projects conducted at or sponsored by the College.

Both the St. Olaf *Code* and the federal Common Rule reflect three ethical principles identified by the federal government as particularly relevant to research projects involving human subjects.<sup>3</sup> These three principles are as follows:

- *Respect for persons.* “Respect for persons” means two things: valuing each person’s autonomy (meaning his or her ability to deliberate about and act upon his or her own goals), and protecting those whose ability to make free and informed choices may be limited by their age, mental abilities, or life circumstances. This principle requires that projects with human subjects be designed to ensure voluntary and informed participation, with appropriate protections for those subjects with limited autonomy.
- *Beneficence.* “Beneficence” means taking steps to ensure the well-being of others. This principle requires that projects with human subjects be designed so as to maximize possible benefits and avoid, or at least minimize, possible harms.
- *Justice.* “Justice” means that both the benefits and burdens of research are fairly distributed. This principle requires that projects with human subjects be designed so that

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<sup>1</sup> St. Olaf is legally obligated to follow the Common Rule for all projects meeting the federal definition of “research with human subjects.” The federal definition of research is explained in a separate St. Olaf document, *Jurisdiction of the St. Olaf IRB*. The legal obligation to follow the Common Rule derives from the federal regulations themselves and from the Federalwide Assurance the College filed with the Office of Human Research Protections in the Department of Health and Human Services.

<sup>2</sup> For a description of the different kinds of projects with human subjects and the different entities responsible for reviewing them for consistency with the St. Olaf *Code*, see “*Who Needs to Review My Project?*” *Determining the Appropriate Review Procedure for a Human Subjects Project*.

<sup>3</sup> For a complete discussion of these principles, see *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 1979) and available on the website of the federal Office of Human Research Protections in the U.S. Department of Health and Human Services (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm#xbasic>).

the process of selecting subjects does not give undue advantages or disadvantages to any one group or class of prospective participants.

These three principles give rise to four basic requirements for protecting human subjects. The discussion of each requirement explains the ethical concerns that give rise to the requirement; steps that investigators commonly take to meet the requirement; and considerations that reviewers of human subjects project proposals should bring to bear in determining whether these steps will provide adequate and appropriate protection for the subjects.

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### **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)].

#### ***What concerns does this requirement address?***

Projects with human subjects impose some costs and/or risks of harm to the subjects, with the type, magnitude, and probability of such costs and risks heavily dependent on the design of the research.

1. **Project costs.** Project costs to subjects generally include their time, their energy, and sometimes their convenience. Most projects impose some of these, particularly time costs.<sup>4</sup>
2. **Different kinds of project risks.** A *risk* is the possibility that subjects will experience some type of discomfort or harm as a result of participating in the project. Projects vary in both the type and seriousness of risk subjects are asked to bear. Types of risk associated with project participation include the following:
  - *Psychological risks:* “Participation in research may result in undesired changes in thought processes and emotion....Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one’s own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence.... Stress may also be induced when the researchers manipulate the subjects’ environment – as when ‘emergencies’ or fake ‘assaults’ are staged to observe how passersby respond....[or when the research involves] an element of deception” (*IRB Guidebook*, Ch. 3, p. 4). Embarrassment, stress, guilt, or other psychological harms may also occur when a subject experiences an invasion of his or her privacy (for example, through covert observation) or

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<sup>4</sup> Some project designs do not require any time or effort from subjects, such as projects involving the analysis of existing data about the subjects or covert observational projects. However, most human subjects projects involve some kind of interaction with the subjects, and it is that interaction that creates costs for the subjects.

a breach of confidentiality (for example, when private information about a subject is shared with another party without the consent of the subject).<sup>5</sup>

- *Social and economic risks*: “Some invasions of privacy and breaches of confidentiality may result in embarrassment within one’s business or social group, loss of employment, or criminal prosecution. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. Some social and behavioral research may yield information about individuals that could ‘label’ or ‘stigmatize’ the subject” (*IRB Guidebook*, Ch. 3, p. 6).
- *Physical risks*: “Medical research often involves exposure to minor pain, discomfort, or ... harm from possible side effects of drugs. All of these should be considered ‘risks’ for purposes of IRB review” (*IRB Guidebook*, Ch. 3, p. 4).

3. **Different levels of project risk.** The *magnitude* and *probability* of such risks are also of concern in projects with human subjects. A project is considered to impose **minimal risk** when “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” [45 CFR 46.102 (i)]. An IRB must ascertain whether the anticipated risks associated with participation in the project have been minimized, most often “by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk” [45 CFR 46.111 (a) (1)]. The greater the magnitude and probability of risk to the subjects, the greater the “burden of proof” on the investigator to demonstrate that potential benefits are commensurate with the anticipated risks.
4. **Special risks for vulnerable populations.** To complicate matters further, different subjects may experience different types or levels of risk from the same research procedure. The federal government is particularly concerned with the protection of **vulnerable populations**, such as minors (persons under age 18), prisoners, pregnant women, mentally disabled persons, residents of long-term care facilities, patients in health-care facilities, and “economically or educationally disadvantaged persons” [45 CFR 46.111 (a) (3)]. Such vulnerable persons may be at greater risk of psychological, social, economic, or physical harm from a research project that would impose only minimal risk on other participants. Investigators are expected to include in their study design “additional safeguards to protect the rights and welfare of these subjects” [45 CFR 46 111 (b)]. There are additional federal regulations protecting the interests of human subjects under age 18 [45 CFR 46 Subpart D]; investigators whose projects involve minors should make sure their project designs incorporate these additional protections.
5. **Project benefits.** Just as the type, magnitude, and probability of risk are of concern in human subjects projects, so are the type, magnitude, and probability of research *benefits*. There are two types of benefit that may accrue from a project: **benefits to society** (or to a specific community within the broader society), and **benefits to the subjects themselves**.<sup>6</sup>

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<sup>5</sup> *IRB Guidebook*, Ch. 3, p. 5.

<sup>6</sup> *IRB Guidebook*, Ch. 3, p. 9

Typically, societal or community benefits are defined in terms of the knowledge or understanding the project is intended to produce, which may lead to improved health, safety, satisfaction, economic security, etc. For human subjects projects that are primarily pedagogical, the principal benefit may be the enhanced education of the project investigators and their classmates. Sometimes participation in a project conveys benefits to the subjects themselves beyond the knowledge that the project as a whole is intended to generate. For example, a thought-provoking questionnaire may be intellectually stimulating to the survey respondents, or may make the respondents aware of services or resources with which they were previously unfamiliar.

6. **Quality of project design.** The magnitude and probability of research benefits depend in large part on the quality of the design of the project. Although it is *not* the responsibility of a project's ethics reviewers to assure the scientific merit of a proposed protocol, there is no question that the quality of the research design will affect both the level of risk for the subjects and the likelihood that the project will actually deliver the anticipated benefits. Reviewers cannot determine whether the risks of a project have been minimized, or whether the benefits of a project outweigh its risks, without careful consideration of its methodological merits.<sup>7</sup>

***What steps should investigators take to meet the Risk/Benefit requirement?***

1. **Anticipate risks and benefits accurately.** Make sure risks and benefits are clearly and accurately anticipated and described in the application. Have all risks been identified? Is the project as designed really likely to achieve the anticipated benefits?
2. **Determine whether risks can be further reduced.** If a project involves more than minimal risk, consider whether an alternative project design could achieve similar benefits. For example, can questions be rephrased to reduce risks to the subjects? Is deception a necessary component of the investigation?
3. **Determine whether costs and risks are justified.** Even projects with minimal risk typically impose some costs on the subjects – at a minimum, the time required to participate in the project. Are the anticipated benefits worth these cumulative costs? The higher the cost and risk of the project, the greater the burden of proof on the investigator to justify the merits of the investigation.
4. **Make provisions for any special risks posed to vulnerable participants.** If a project involves vulnerable persons (particularly minors), consider whether the anticipated risks or benefits might be experienced differently by these project participants, and whether adjustments in the project protocol might be warranted by the characteristics of those participants.

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<sup>7</sup> See Amdur, *Institutional Review Board Member Handbook*, Ch. 3-1 for a fuller treatment of this point.

***What should reviewers consider in determining whether a proposed project meets the Risk/Benefit requirement?***

1. Have the costs, risks and benefits of the project been accurately identified and described? Has the likelihood of anticipated risks and benefits been accurately portrayed?
2. Does the project expose the subjects to more than minimal risk?
3. Have reasonable provisions been made to minimize costs and risks and to maximize benefits?
4. Is there a vulnerable population involved in the project? Has the investigator considered, and made appropriate provision for, the possibility that their level of risk might be different than the level of risk experienced by other participants?
5. Are the benefits to the participants and to society (or to a subset of society) worth the costs and risks to the subjects?
6. Should the project be monitored during and after the conduct of the project to ensure that the risk/benefit ratio remains appropriate?<sup>8</sup>

In the end, ethics reviewers must determine for any given project whether the risks to the subjects are reasonable in relation to the anticipated benefits. There is no formula for making this determination; however, the federal *IRB Guidebook* offers this perspective (Ch. 3, p. 10): “In [projects] where no direct benefits to the subject are anticipated, the IRB must evaluate whether the risks presented by procedures performed solely to obtain generalizable knowledge are ethically acceptable. There should be a limit to the risks society asks individuals to accept for the benefit of others. [On the other hand,] IRBs should not be overprotective. While the IRB must consider the importance of the knowledge that may result from the [project], the IRB’s appreciation of that importance may, at times, be limited. If only minimal risks are involved IRBs do not need to protect competent adult subjects from participating in research considered unlikely to yield any benefit.” This is good advice not only for members of an Institutional Review Board, but for anyone responsible for evaluating the ethical implications of a proposed project.

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<sup>8</sup> List of reviewer considerations adapted from the *IRB Guidebook*, Ch. 3, p. 11.

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**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)].<sup>9</sup>

*What concerns does this criterion address?*

1. **Exploitation.** Exploitation occurs when *the way subjects were selected results in some categories of persons bearing a disproportionate share of the burdens (risks and costs) of project participation*. Ethical and regulatory concern has focused on ways to address the disproportionate selection of some classes of persons for use in research “simply because of their easy availability, their compromised position, or their manipulability” (*IRB Guidebook*, Ch. 3, p. 24). Groups rendered vulnerable because they fit one or more of these descriptors include: students, prisoners, patients in mental institutions, military personnel, patients, institutionalized persons, patients dependent on a particular physician or facility, members of racial and ethnic minorities, or persons disadvantaged educationally, socially, or economically.

The regulations require, in general, that investigators select subjects who are adult, legally competent, non-institutionalized, and independent persons, unless the purposes of research can only be served by involving children, incompetent, institutionalized, or otherwise dependent persons. In addition, persons already burdened in life in significant ways (e.g., by disease, disability, economic and educational disadvantage) are not to be involved in research without special justification. The onus is on the investigator to justify the inclusion of any such groups in proposed research. If they are to be used in research, the purpose of the research must be necessarily related to that group and hold the prospect of benefit for that group.

2. **Exclusion.** Exclusion occurs when *the way subjects were selected results in some categories of persons being prohibited from realizing the benefits of the project*. Unfairness in the distribution of research burdens and benefits may occur not only in disproportionately bearing the burdens of research, but in being disproportionately excluded from its benefits. If a population group is underrepresented in research, the benefits of research may not extend to that group, and that group may actually be harmed by the illicit extension of research

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<sup>9</sup> The portions of the federal regulations that apply most directly to the selection of subjects are these:

*“Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.”* [45 CFR 46.111(a)(3)]

*“When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.”* [45 CFR 46.111(b)]

outcomes to it. Such has been the case historically with minority groups and women in the U.S. Hence, a further element of equitable subject selection includes the adequate representation of all groups who might benefit from research outcomes (NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 *Federal Register* 14508. 28 March 1994). Again, the onus is on the investigator to show that subject selection enables all who can benefit from the research to do so.

3. **Overprotection.** Overprotection occurs when *the way subjects were selected results in some categories of persons (usually vulnerable populations) being unnecessarily excluded from participation.*<sup>10</sup> The investigator faces an often difficult balancing act in implementing the duties to avoid over-inclusion of groups in the burdens of research and over-exclusion through under-representation of groups from the benefits of research. The goal of proportionately distributing research burdens and benefits must be managed without paternalistically overprotecting vulnerable groups.

#### *What steps should investigators take to meet the Subject Selection requirement?*

1. **Select subjects so as to match the burdens of participation with project benefits as closely as possible.** Whenever possible, recruit subjects so that those who accept the risks or burdens of being research subjects will also be the ones who share in its benefits.
2. **Avoid unwarranted exclusion of subjects.** Assure that study design provide for the adequate representation of women and minorities in the subject population, so that the findings will enable these groups to share in the benefits of the research.
3. **Avoid overprotection of subjects.** Seek ways to avoid paternalism as you provide adequate protections for members of vulnerable groups.

#### *What should reviewers consider in determining whether an investigator has met the Subject Selection requirement?*

1. Are vulnerable groups involved? If so, which one(s)? Do special federal research regulations apply to this group?
2. What groups bear the burdens and are most likely to benefit from this project?
3. What is the nature of the project, such that the use of a specific subject population may be justified/unjustified? Are general inclusion and exclusion criteria clear and justifiable?

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<sup>10</sup> The Belmont Report was written in response to failures to respect the autonomy, protect the interests of, and be fair to, persons participating as subjects in human research. The federal regulations pertaining to subject selection were primarily intended to rectify injustice (unfairness) in the distribution of research burdens and benefits by providing guidance for the equitable selection of human subjects. The history of human research in the U.S. and elsewhere had involved significant exploitation of disadvantaged and vulnerable populations in research that only benefited others. In short, the systematic, disproportionate inclusion of some groups in research had led to the inequitable distribution of research burdens and benefit among us: some had borne the burdens of research while others had reaped the benefits of their sacrifices.

4. Are women or minorities excluded, and if so, is their exclusion justifiable?
5. Will recruitment methods yield a representative study population in relation to the purposes of the project?
6. Do subject recruitment methods disproportionately target any single group?
7. Do the characteristics of some subject groups render them at greater risk than others, given the nature of the project?
8. If the project involves members of vulnerable populations, could the project be conducted with less vulnerable subjects?
9. Is the selection process paternalistic and overprotective of vulnerable groups?
10. After all the above issues have been considered, is the distribution of burdens and benefits fair, or is it disproportionate in any way that calls for justification?<sup>11</sup>

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**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)].

*What concerns does this requirement address?*

1. **Respecting subjects' privacy.** Privacy pertains to the nature of the information that an investigator *obtains* about the subjects and the circumstances under which that information is obtained. *The federal IRB Guidebook* defines privacy as "having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others" (ch. 3, p. 28). Normally, subjects are able to control the information they share about themselves through the informed consent process. However, as noted below in the discussion of Requirement 4, it is not always possible for an investigator to secure informed consent in advance of a project. Examples include projects in which an investigator analyzes existing records with identifying information on them (names, ID numbers, etc.) without the knowledge of the people whose records are being analyzed, or observational studies in which people do not know that they are being observed and that information about them is being collected for project purposes. Investigators should seek to minimize potential invasions of privacy, and there are a number of steps they can take to do so, as described below.
2. **Ensuring the confidentiality of the subjects' information.** Confidentiality pertains to the nature of the information that an investigator *shares* about the subjects. Most people think

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<sup>11</sup> Adapted from the *IRB Guidebook*, Ch 3, p. 27, and Amdur, *IRB Member Handbook*, p. 46.

that confidentiality means “non-disclosure of subject-specific information.” However, that is not quite its meaning (even though most of the time that is what investigators actually do). Rather, confidentiality means *respecting the understanding the subjects had about who will have access to their personal information at the time the subjects disclosed the information*. Confidentiality is really about an investigator honoring a prior agreement with the subjects about what can be shared with whom. On occasion, subjects agree in advance for others to know that they participated in a project and even to know the specifics of the information they provided and the fact that they provided it. In these cases, an investigator does not violate confidentiality if he or she discloses the identities of the subjects or reports data in a way that would allow others to identify the source of subject-specific information (for example, including a quote from an interview in a project report and attributing the quote to a specific individual). This is why it is not entirely accurate to say that confidentiality is *synonymous* with non-disclosure, even though an investigator’s efforts to ensure confidentiality will often *result in* non-disclosure.

In most cases, the prior agreement between the investigator and the subjects about what can be shared and with whom is made explicit in the informed consent process. However, as noted above, some project designs do not include the usual steps to secure informed consent. For example, when an investigator is analyzing existing records that contain **personally identifiable information** – that is, records that include identifiers such as names, ID numbers, or extensive demographic information, so that information about the subject can be identified as belonging to the subject – the subjects are often not notified that someone is collecting this information and planning to share it in a study. *In these cases, investigators should assume a prior agreement of non-disclosure*. In other words, they should assume that if the subjects had been given the opportunity to give informed consent to the use of their information in a human subjects project, they would have done so with the understanding that project results would not be shared in a way that would allow others to identify them. Usually, this means that investigators must not disclose the identities of the individuals involved in their project, and must not present project results in a way that would allow others to identify an individual subject, even accidentally. Again, there are specific steps investigators can take, throughout the course of a project and after it has ended, to maintain the confidentiality of the information they gather.

### ***What steps should investigators take to meet the Privacy and Confidentiality requirement?***

The specific steps investigators can take to minimize invasions of privacy and maximize confidentiality depend on the design of the project and the institutional context (if any) within which it is conducted. Below are some common options investigators should consider.

#### *Respecting privacy*

1. **Secure appropriate authorization for access to institutional records.** If the project requires access to personally identifiable records without the written explicit permission of the subjects (transcripts, medical records, or other documents where the subjects’ identities are recorded on the documents), investigators must secure written approval for such access from an appropriate authority from the institution. Some federal laws, such as FERPA (the

Family Educational Rights and Privacy Act) and HIPPA (the Health Insurance Portability and Accountability Act), impose additional requirements on investigators seeking access to private information in educational or medical records.

2. **Consult with institutions about their own privacy protections.** Investigators should consult with the institution to determine if there are institutional policies or practices regarding access to personally identifiable records that would reduce the potential for invasion of privacy. For example:
  - The institution may be willing to contact prospective subjects and ask their permission to provide their names and/or data to the investigator.
  - At the time the record is initially created, the institution may routinely provide an opportunity for people to consent (or withhold consent) to possible use of their records in human subjects projects, and to specify the conditions of such use.
  - The investigator may become an employee of, or consultant to, the institution so that he or she is authorized to see and use the records within the parameters of institutional policy.

#### *Maintaining confidentiality*

1. **If possible, ask subjects to provide information anonymously.** When subjects provide information anonymously, the investigator can't determine which items of information came from which individuals. This virtually eliminates the possibility of breach of confidentiality, since the investigator cannot share information he or she does not have (who said what, who believes what, or who did what).
2. **If subjects cannot provide information anonymously, “anonymize” data as it is gathered if it is possible to do so.** Anonymizing data refers to the process of removing identifiers as the data are recorded by the investigator, so that the *records* in the investigator's possession are anonymous, even though the information was identifiable when the investigator initially gained access to it. For example, if the project involves the analysis of information from personally identifiable records, the investigator can detach or remove names or other identifiers from the data before recording it. If the records are being photocopied, the investigator can block out names and ID numbers. If the project involves written questionnaires, cover sheets with the names and addresses can be removed from the completed questionnaires and keep the cover sheets separate. If the project involves a face-to-face interview, investigators can record the subject's answers but not the subject's name or other identifying information. Another approach that comes close to anonymizing the data in the recording phase is to use tracking numbers instead of names, social security numbers, student ID numbers, or other identifiers. The investigator invents his or her own set of tracking numbers, assigns a number to each person's data, removes all the other identifiers from the data, and keeps a separate list of the names (secured as described below) associated with each tracking number. The list can then be destroyed at the conclusion of the project.
3. **Do not disclose the identities of the subjects who participated in the project without their consent.** Unless subjects have agreed in advance that investigators may share the

names (or other identifiers) of project participants with a third party, investigators must not share that information, whether in formal reports or presentations or in casual conversation.

4. **Do not include personally-identifiable information about individual subjects in project reports without their consent.** Some project designs simply don't permit subjects to be anonymous, either when they provided their information or when the investigator recorded it. Investigators may need to keep the identities of the subjects linked to the subjects' data in their own project records to support the analysis of the data. When that is the case, investigators need to be especially vigilant in ensuring confidentiality. Unless the subjects have consented to the release of their personally-identifiable information, the investigator is obligated to ensure that none of his or her presentations, papers, or other project reports include material that would permit others to identify any of the subjects. Not only does this mean that investigators should not include names, ID numbers, or other obvious identifiers; it also means that investigators should use caution in providing *any* subject descriptors (age, ethnicity, organizational affiliations, etc.). This is especially important if the report includes individual-level data (for example, quotes or paraphrases from interviews, or descriptions of the observed behavior of specific individuals) or aggregated data from small subgroups.
5. **Keep the subjects' data physically secure.** Investigators also need to make provision for the storage and/or disposal of the data during and after the conduct of a project. It is common to keep identifiable private information in locked cabinets to which only specific people are authorized access, and to destroy the records when the final report is prepared (and to say so in the informed consent documents, when informed consent has been sought).

Additional steps to protect privacy and ensure confidentiality may be required by projects that involve vulnerable populations, the investigation of sensitive information, or information that may put subjects at risk of any of the harms described in Requirement 1. Investigators should consult the relevant federal regulations and the *IRB Guidebook* for guidance in these cases.

***What should reviewers consider in determining whether an investigator has met the Privacy and Confidentiality requirement?***

1. Does the project involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy? Would reasonable people be offended by such an intrusion? Can the project be redesigned to avoid the intrusion?
2. If privacy is to be compromised, does the importance of the project objective (and the quality of the project design) justify the intrusion? What, if anything, will the subject be told later?
3. If the investigator wants to review existing records to select subjects for further study, whose permission should be sought for access to those records (the institution maintaining the records? the subjects themselves?); How should the subjects be approached (by the researcher? the institution?)?
4. Will the investigator be collecting sensitive information about individuals? If so, have they made adequate provisions for protecting the confidentiality of the data through coding,

destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study? If the information obtained about subjects might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information, can a grant of confidentiality be sought from a federal or state agency to protect the research data and the identity of the subjects from subpoena or other legal process?

5. Are the investigator's disclosures to subjects about confidentiality adequate? Should documentation of consent be waived in order to protect confidentiality?<sup>12</sup>

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#### **REQUIREMENT 4: APPROPRIATE PROVISIONS FOR OBTAINING INFORMED CONSENT**

**In most cases, investigators must secure the legally effective informed consent of the subject<sup>13</sup> before involving the subject in the project.** [45 CFR 64.111 (a) (4) and (5); 45 CFR 46.116; 45 CFR 46.117]

#### ***What concerns does this requirement address?***

The purpose of the informed consent provisions in the federal human subjects regulations is to ensure that prospective participants (or their legally authorized representative – see note 6 below) “will understand the nature of the [project] and can *knowledgeably* and *voluntarily* decide whether or not to participate” (emphasis added).<sup>14</sup> Investigators conducting projects which do not constitute “research” as federally-defined, but which nevertheless involve human subjects, are also obligated to secure the informed consent of the participants, as appropriate to the project.

The informed consent provisions in the federal regulations address the following concerns:

1. **Sufficiency of information provided to the subjects.** In order to make an informed decision about whether to participate in a project, a prospective subject needs adequate information about the nature of the project, its possible consequences for participants, and the investigators and their institutional affiliation. The federal regulations include a specific list of things prospective participants need to know about a project ([45 CFR 46.116 (a) and (b)] – see below) in order for their consent to be considered genuinely “informed.”
2. **Understandability of information provided to the subjects.** The information provided to prospective subjects must be in language that the subjects understand [45 CFR 46.116]. This in

<sup>12</sup> Adapted from the *IRB Guidebook*, Ch. 3, p. 37.

<sup>13</sup> Some subjects, such as minors (under age 18) or the mentally disabled, must provide consent through a “legally authorized representative,” defined in the federal regulations as “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the [project]” (45 CFR 46.102 (c)). The language of this section of the Code assumes that “subject” includes the subject’s legally authorized representative.

<sup>14</sup> *IRB Guidebook*, ch. 3, p. 11

turn requires an investigator to be knowledgeable about the subjects themselves so the language that is used to explain the project can be tailored to their background, age, experience, or other characteristics that might affect the subjects' ability to understand the information presented by the investigator. When English is not the subjects' first language, the project information and any forms they are asked to complete will need to be translated.

3. **Voluntary nature of any decision to participate.** People need a chance to process the information they are given about the project and to think through the merits of their participation before they decide whether to take part. Consequently, the project itself, the information provided to prospective participants, and the circumstances under which the subjects are asked to participate, must be designed to provide "sufficient opportunity to consider whether or not to participate" [45 CFR 46.116]. In addition, in order to "minimize the possibility of coercion or undue influence," prospective participants must be assured that they will neither be penalized for not participating, nor unduly rewarded for participating, and that they can change their minds at any point in the course of a project.
4. **Appropriate documentation.** Some kinds of projects require that project information be provided to prospective participants in writing. Some also require that subjects sign a form indicating that they have received and understood the project information and voluntarily consent to participate. For other projects, oral information and/or oral consent may be sufficient, although provisions must be made to ensure that the same information is provided to each prospective participant even if it is provided orally.
5. **Preservation of the subjects' legal rights and recourse.** The consent given by prospective participants may not include any "exculpatory language" in which subjects waive, or appear to waive, their legal rights, or release from liability or negligence the investigator, the sponsor, or the institution under whose auspices the project is being conducted [45 CFR 46.116].
6. **Circumstances warranting alteration in informed consent procedures.** Some project designs make it difficult or impossible to obtain informed consent without significantly compromising the anticipated benefits of the project. Examples might include projects involving covert observation, experiments requiring temporary deception of subjects, or analysis of existing data. Other projects might expose participants to *greater* risk if participants provide their consent in writing (for example, projects that collect information from political dissidents). The federal regulations governing human subjects protections include stringent conditions which a project must meet in order for reviewers to waive the normal consent requirements for project participation [45 CFR 46.116 (d)].

***What steps should investigators take to meet the Informed Consent requirement?***

1. **Determine whether project information should be provided in writing.** Investigators conducting any type of human subjects project must provide project information to prospective participants, except in exceptional circumstances as described above. Project information must be provided **in writing** if the project is a **research project** or if the project poses **more than minimal risk** (see Requirement 1). Written project information may be

provided as a detachable cover sheet or as introductory material to a written questionnaire or set of instructions, depending on whether the project information is accompanied by a written consent form.

2. **Provide basic information about the project in an accurate and understandable way** [45 CFR 46.116(a)]. The question the investigator should ask him- or herself in developing the project information statement is, “What would a subject need to know about my project in order to give fully informed consent to participate?” At a minimum, project information should include the following (even for projects with minimal risk):
  - 1) *Project purpose*: A brief explanation of the purposes of the project (which may include fulfillment of a course requirement for student projects).
  - 2) *Project type*: If the project is a research project as federally defined (see *Jurisdiction of the St. Olaf IRB* and *The Protection of Human Subjects in Student Projects* for a discussion of the criteria a project must meet in order to be considered a “research” project), a statement that the project is, or involves, research. **If the project does not fall within the federal definition of “research,” the word *research* should not be used to describe the project in the project information or in other documents associated with the project.** Related terms like “inquiry,” “investigation,” “study,” “exploration,” or “examination” are good alternatives; they do not carry the regulatory freight carried by the term “research.”
  - 3) *Supervising faculty*: If the project is being conducted by students, a statement to that effect. The name and department of the faculty member under whose supervision the project is being conducted should also be provided.
  - 4) *Procedures*: A description of what the subjects will be asked to do (complete a questionnaire, participate in a focus group, taste food substances, answer oral questions, etc.) and/ or how information will be collected about the subject (weighing, specimen collection, observation, etc.).
  - 5) *Costs to the subjects*: A description of likely costs, particularly the length of time subjects will be asked to commit to the project, or other inconveniences subjects may experience.
  - 6) *Risks to the subjects*: If the project involves more than minimal risk (see above), a description of any reasonably foreseeable risks or discomforts the subject may experience. If there are no such risks or discomforts, no statement is necessary, although some investigators choose to include a statement indicating that there are no risks or discomforts anticipated.
  - 7) *Audiences for dissemination*: A statement describing the audience(s) with whom project results will be shared.
  - 8) *Whether and to whom the subject’s participation in the project would be disclosed*: If the subject’s participation in a project would be disclosed to any others (even if personally identifiable information provided by the subject is not disclosed), a statement describing such disclosure. Many investigators include an assurance of non-disclosure if no disclosure is planned.

- 9) *Whether the subject's information will be identifiable and if so, to whom:* Subjects need to know whether anyone, including the investigator, will be able to determine who said or did what, or who experienced what. If so, subjects will need to know which others, and how they will know (examining the original data? reading or listening to reports?). In general, project information should include a version of one of the following statements about the identifiability of the subject's information:
- (a) *That the subject's information will be anonymous.* If data are collected with no identifying information at all included with the subject's data, so that even the investigator cannot identify the subject's data as belonging to the subject, then the project statement should indicate that subjects will provide their information anonymously.
  - (b) *That although the subject's information will not be anonymous, only the investigators will be able to link the identity of the subject to the subject's data.* If the data collected from the subjects include any identifying information (such as name, ID number, social security number, etc.) or demographic information that, when combined with other information, could permit subjects to be identified, the project statement should describe how the investigator will ensure that no one else will be able to link the subject's identity to the subject's data. For example, the statement could indicate that all potential identifiers will be removed when the data are collected and/or reported, or that no individual-level data, or data from small groups with distinctive demographic features, will be reported.
  - (c) *That others may be able to link the subject's identity to the subject's information.* As noted in the discussion of Requirement 3, some kinds of projects are designed so that subjects' identities may be disclosed to others. In these cases, the project information statement must indicate that clearly and explain how and why that is likely to occur.
- 10) *Project benefits:* A description of any benefits to the subjects (such as the chance to reflect on important topics), and/or to the wider community, which may reasonably be expected from the project.
- 11) *Voluntary nature of initial decision to participate:* A statement that the subject is free to choose to participate, or not to participate, in the project, and that the subject will not be penalized or lose any benefits to which the subject may otherwise be entitled if the subject chooses not to participate.
- 12) *Voluntary nature of continued participation:* A statement that the subject is free to discontinue participation at any time over the course of the project, or to participate only in part (e.g., by choosing not to answer selected questions), even after having initially consented to participate, without any penalty or loss of benefits.
- 13) *Investigator contact information:* Complete contact information (name, telephone, email address at a minimum) for the investigator and, if appropriate, the investigator's supervisor, for questions or concerns about the project.
3. **Provide additional information as appropriate to the project** [45 CFR 46.116(b)]. Some project designs require that additional information be provided to prospective participants in order for their consent to be fully informed. Such information may include:

- 1) *Alternative procedures:* For research projects involving treatments that may benefit the subjects, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects.
  - 2) *Compensatory treatments:* For research project involving more than minimal risk, an explanation as to whether any compensation and/or medical or other treatments are available if injury (physical, psychological, social) occurs, and if so, what they consist of and/or where further information may be obtained.
  - 3) *Information on the subjects' rights:* If the project poses more than minimal risk, an explanation of whom to contact regarding the subject's rights in the event of a project-related injury or harm.
  - 4) *Possibility of unforeseen risks:* A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable (usually associated with medical research).
  - 5) *Possibility that subject's participation would be terminated:* A description of any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent (but still without penalty to the subject).
  - 6) *Consequences of discontinuation of participation:* The consequences of a subject's decision to withdraw from the project and procedures for orderly termination of participation (but still without penalty to the subject).
  - 7) *Disclosure of new information that might affect consent:* A statement that any significant new findings that emerge during the course of the project which may affect the subject's willingness to continue participation will be provided to the subject.
  - 8) *Sample size:* In some cases, participants should know the number of subjects involved in a project before deciding to participate.
4. **Provide a written consent form, if appropriate.** Investigators must secure written consent if the project involves **more than minimal risk** or if a **legally authorized representative** of the subject is required to provide consent (as in the case of minors, for example). A written consent form must include the following:
- A statement that the subject has read and understood the project information statement.
  - A statement indicating that the subject will be offered a copy of the information statement and the signed consent form to keep.
  - A line for the signature of the subject, followed by the date of the signing (do not make an "X" to show where to sign).
  - A line for the signature of the investigator, followed by the date of the signing.

***What should reviewers consider in determining whether an investigator has met the Informed Consent requirement?***

1. Does the project information provided to the participants provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?
2. Is there a vulnerable population involved in the project?
3. Is the language and presentation of the information to be conveyed appropriate to the subject population? (Consider the ages, experience, and language capabilities of the subjects.)
4. Are the timing and setting of the explanation of the project conducive to good decision-making? Can anything more be done to enhance the prospective subjects' comprehension of the information and their ability to make a free and informed choice?
5. Who will be explaining the project to potential subjects? Are there power or status differences between the investigator and the prospective subjects that might make it advisable for someone other than, or in addition to, the investigator to be present and/or to provide the information?
6. Should subjects be re-educated and their consent required periodically?
7. Should the IRB monitor incoming data to determine whether new information should be conveyed to participating subjects? How often should this occur? Who is responsible for bringing new information to the attention of the IRB between scheduled reviews?
8. If the investigator requests a waiver of the normal informed consent procedures, does the importance of the project justify the waiver? Is more than minimal risk involved? Can the research design be modified to eliminate the need for deception or incomplete disclosure? Will subjects be given more information after completing their participation? Would the information to be withheld be something prospective subjects might reasonably want to know in making their decision about participation?<sup>15</sup>

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<sup>15</sup> Issues reviewers should consider are all quoted or paraphrased from the *IRB Guidebook*, ch. 3, pp. 22-23.

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CONCLUSION

Although this Code provides a great deal of guidance, it nevertheless includes only basic information about human subjects protections for the kinds of projects most commonly conducted at St. Olaf. **All other provisions of the federal Common Rule for the Protection of Human Subjects are incorporated by reference into the St. Olaf College Code of Ethics for Projects with Human Subjects.** Some research projects will include design features that are not addressed in the *Code* and/or that will necessitate additional protections for the subjects. Investigators should consult the Common Rule for the Protection of Human Subjects at 45 CFR 46 and the *Institutional Review Board Guidebook* prepared by the Office of Human Research Protections in the U.S. Department of Health and Human Services (hereafter the *IRB Guidebook*) for additional guidance on exceptional projects.

Additional information about the St. Olaf Institutional Review Board, intermediate review committees, determining the appropriate review procedure for a particular project, application forms for review of project proposals, and links to the Common Rule, the federal Office of Human Research Protections, and other useful resources, are available on the website for the IRB:

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

Prospective applicants are encouraged to contact any member of the IRB with questions about project design, preparation of an application of review, or any other aspect of human subjects protections.