College of Saint Elizabeth Institutional Review Board (IRB) User's Guidebook[1]

August 27, 2012

Table of Contents

[1] CSE's original guidebook was published in June 2004. The original guidebook was developed by the IRB Steering Committee of the Academic Life Committee, consisting of Jean Burge, Herman Huber, Louise Murray, and Eileen Specchio. The Steering Committee adapted the IRB manuals of the University of New Mexico and Woffolk College, retrieved Dec 1, 2003. The IRB acknowledges contributions from Princeton University and Carnegie Mellon University in developing the 2009 and 2012 revisions. In 2012, Thomas Barrett, Paul LaChance, Anne Langan, Susan Lasker, Ed Martone, Margaret Mittricker, Louise Murray, Michael Renahan, contributed to the revised guidebook.

1. Introduction: Relevance to the College Mission and Role of the IRB

A. Relationship of IRB to the Mission of the College

In fulfilling its commitment to academic excellence, the College of Saint Elizabeth (CSE) encourages the conduct of scholarly research by faculty, staff, and students. To ensure that all research conducted under the College auspices meets the highest ethical standards, the College has established an Institutional Review Board (IRB) to protect the rights, privacy, and well-being of all persons involved as research subjects. This commitment to protecting human subjects is an expression of the missions of the College and the Sisters of Charity, both of which place a primacy on the dignity of all human persons.

B. Underlying Ethical Principles

Along with respecting the right of faculty, staff, and students to full academic freedom in research, The College of Saint Elizabeth is committed to adhering to the basic ethical principles underlying *The Belmont Report:*[2] respect for persons, beneficence, and justice:

Respect for Persons: This principle involves the recognition of the personal autonomy and dignity of individuals and the need for special protection of individuals with diminished autonomy. Under this principle, individuals must be given sufficient information to decide whether to participate in a study; they must be able to comprehend the information; and their consent must be voluntarily given, free from coercion and undue influence. IRBs expect researchers to be particularly sensitive to these factors when vulnerable subjects are involved, to ensure that extra measures are taken to protect the immature and incapacitated, and may even require that they be excluded from participating in certain research. Respect for persons also means honoring the subjects' privacy and confidentiality.

Beneficence: This principle entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle requires assessing the nature and scope of the risks and benefits, and systematically assessing the risks and benefits. All possible harms must be considered, not only physical and psychological injury. All possible benefits, including societal benefits that might be gained from research, must also be considered.

[2] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report*. 1979.

Benefits to the subjects, or generalizable knowledge to be gained from the research, shall always outweigh the risks. In assessing the risks and benefits, the appropriateness of involving vulnerable populations is considered.

Justice: This principle of justice requires that the benefits and burdens of research be distributed fairly. Subjects must be fairly selected, and may not be selected either because they are favored by a researcher or held in disdain. Social justice requires an order of preference in the selection of classes of subjects, for example, adults before children. The principle cautions that researchers shall not systematically select subjects because of their easy availability, their compromised position, or their social, racial, sexual, or economic position, or because of cultural biases institutionalized in society. Investigators shall base inclusion criteria on those factors that most appropriately address the research problem.

C. Role of IRBs in Higher Education

Within U.S. higher education, each institution's Institutional Review Board has responsibility that research protocols protect human subjects. These IRBs, which are comprised mainly of faculty, review all research proposals according to pre-established guidelines. The College of St. Elizabeth encourages the conduct of research in each department, and in collaboration with other educational institutions, agencies, and organizations.

D. Role of CSE IRB

Any research that systematically collects data directly from human beings through such methods as surveys, interviews, focus groups, and/or observations may be appropriate for IRB review. At the College of Saint Elizabeth all dissertations, masters theses, and undergraduate honors research projects that collect data from human subjects should be reviewed by the CSE IRB. At the College of Saint Elizabeth, all data collection efforts must respect the rights and welfare of research subjects/participants, although classroom assignments that require students to collect data are generally exempt from CSE IRB review. (See chapter 3A for further clarification or contact the IRB Chair at irb@cse.edu.)

The IRB is responsible for assuring that: 1) the welfare and rights of human subjects are adequately protected and informed consent given, if necessary; 2) human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research; 3) the necessity and importance of the research outweighs the risks to the subjects; and 4) the researcher(s) is/are qualified to conduct research involving human subjects.

E. Benefits of the CSE IRB

Along with providing a viable means for protecting human subjects in research of varying risks, there are several practical benefits of the CSE IRB. In order to fulfill its mission to train students

for leadership in service disciplines that are research based, the College has an obligation to provide students with experience in negotiating with compliance committees. Second, most peer-reviewed journals in the health and social sciences will accept only manuscripts of research that have been approved by an IRB. Finally, in order to obtain research funding from the Department of Health and Human Services (DHHS), which includes the National Institute of Health (NIH) and the National Institute of Mental Health (NIMH), the grant seeker has to demonstrate that the research proposal was approved by an IRB.

F. Limits of the CSE IRB

Recognizing that regulations, policies, and procedures alone are no guarantee of ethical conduct, the College places ultimate responsibility on individual researchers to make ethical considerations central in the conduct of research and to have a clear understanding of their duties to human subjects.

2. The Structure of the IRB

A. Membership

1. The IRB is composed of nine (9) voting members:
    a. Six are faculty members including one from:
        i. Psychology or Sociology;
        ii. Health-related field (Biology, Nursing, or Nutrition);
        iii. One trained in Ethics;
        iv. Business;
        v. Education; and
        vi. One from any discipline.
    b. One outside member from the community
    c. The College's Health Director of Health Services

d. The College's Director of Institutional Research, who will serve as ex-officio chair.

e. Length of Terms

i. The faculty elects the faculty members for three-year terms.

ii. The outside member also serves for three-year terms and is approved by a majority of the College members of the Committee.

iii. The Directors of Health Services and Institutional Research shall serve as long as they are employed in those positions.

B. Quorum: Five members shall constitute a quorum.

C. Confidentiality: The IRB shall keep all deliberations confidential.

3. Types of IRB Review

A. Exempt Status

1. A number of departments offer courses that require students to undertake projects in which other people serve as subjects. These course projects train students and provide them with a closer view of behavioral/social processes and an opportunity to practice various methods of inquiry. Such projects involve no more than minimal risk to subjects. Therefore, the IRB does not consider them to be subject to review and approval is not required. Research which is regarded as having no more than minimal risk to subjects includes the following:

a. Research in which the risks of harm reasonably anticipated are not greater than those ordinarily encountered in daily life or during the performance of routine procedures in education, business and/or in the practice of psychology and health care;

b. Research on the effectiveness of educational, classroom, and/or instructional strategies, provided that these strategies are familiar and non-intrusive in their implementation;

c. Research using educational tests (cognitive, diagnostic, aptitude, achievement) if subjects' identities are thoroughly protected;

d. Research using survey procedures or interview procedures where subjects' identities are thoroughly protected and their answers do not subject them to criminal and civil liability;

e. Research involving the collection or study of existing data, documents, records, specimens, or other products, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or indirectly.

f. Research on taste and food quality evaluation and consumer acceptance studies involving wholesome foods without additives or foods with additives that are determined safe by the US Food and Drug Administration, the US Environmental Protection Agency, and the US Department of Agriculture.

2. Faculty who assign or approve such projects are responsible for ensuring that no more than minimal risk to subjects is involved. Moreover, academic departments conducting research that qualifies for exempt status shall ensure that faculty introduce students to the existence of the IRB in discussions of research methodologies.

B. Full Review

1. The IRB shall conduct a full review when the research involves more than minimal risk to subjects. Research involving more than minimal risk includes but is not limited to the following:

a. Research which involves the administration of drugs or other substances to subjects;

b. Research involving pregnant women;

c. Research involving subjects with life-threatening physical conditions;

d. Research involving physically intrusive procedures;

e. Research involving deception.

f. Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to subjects; and

g. Research which potentially could put the subject at risk for liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior or attitudes (e.g., illegal conduct, drug use, sexual behavior, alcohol use, prejudice).

2. The IRB shall conduct a full review only when a quorum is present.

C. Expedited Review

1. An expedited review does not require review by the full board and can be conducted between regularly scheduled IRB meetings. In determining whether an expedited review is appropriate, the IRB Chair will consider two criteria:

a. The research must involve no more than minimal risk to the human subjects; and

b. The research must consist entirely of one or more of the following specific activities:

i. Research on individual or group behavior characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects;

ii. Voice recordings made for research purposes, such as investigations of speech defects;[3]

iii. Moderate exercise by healthy volunteers;

iv. The study of existing data, documents, records, pathological specimens, or diagnostic specimens;

v. Research on drugs or devices for which an investigational device exemption is not required;

vi. Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction;

[3] For example: An audio tape on which subjects are asked to speak common words for the purpose of measuring voice timber would qualify for expedited review. A tape of a therapy session with a patient would not qualify for expedited review. Although the research involved an audiotape, the sensitive nature of the contents would require a full review.

vii. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor;

viii. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves)

ix. Collection of both supra-and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

2. When conducting an expedited review, IRB members may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after a full IRB review has been conducted.

3. The chair of the IRB shall advise all IRB members of all research proposals that have been approved using expedited procedures at the next regularly scheduled meeting.

D. Continuation/Renewal

1. The IRB may approve the data collection phase of a research project for a period up to 12 months from the date of IRB approval. Researchers who wish to continue to collect data after the approval period must apply for a continuation/renewal.

2. The IRB shall use expedited review if no changes have been made to the research protocol and no adverse or unexpected reactions or side effects have occurred or are expected.

3. If changes have been made to the research protocol, the full IRB may review the research project.

E. Revision

1. If the investigator, during the course of conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of subjects), the researcher shall notify the IRB Chair immediately.

2. The IRB Chair shall determine the need for additional review, the type of review (full or expedited) and notify the IRB members.

4. Criteria for Approval of Research

A. In order to approve research covered by the policy contained in this guidebook, the IRB shall consider the following:

1. Risks to subjects are minimized;

2. Risks to subjects are reasonable in relation to anticipated benefits;

3. Selection of subjects is equitable in relation to the purpose and context of the research;

4. Informed consent shall be sought from each prospective subject or the subject's legally authorized representative;

5. Informed consent shall be appropriately documented or the rationale for waiver of documentation is appropriate;

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

7. When appropriate, adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of data;

8. Additional safeguards have been included in the study to protect the rights and welfare of vulnerable populations, such as children' prisoners' pregnant women' significantly mentally disabled or institutionalized persons; and

9. Agreement with the IRB's requirements for the reporting of adverse events.

B. The researcher[4] shall demonstrate certification in human subjects' protection. Options for completing an online course in human subjects' protection are provided on the IRB website.

C. If the research is conducted outside the College campus, the Researcher shall provide documentation that the research site has given permission for the study. If the research site has an operating IRB, the Researcher shall obtain approval from both IRBs.

D. The IRB shall document that each approved research proposal met the requirements.

5. Types of IRB Actions

A. Approve

1. The proposal is approved as submitted.

2. The IRB shall notify the researcher in writing.

B. Approved Pending Minor Changes

1. If the required changes are minor, the IRB shall authorize the chair to review the required changes and send formal approval to the applicant(s) when the changes are complete.

2. The IRB shall notify the researcher in writing of the conditions of approval.

C. Deferred Pending Significant Changes

1. The IRB may postpone a decision and ask for more substantive clarification of the study methodology.

2. The IRB shall review the proposal after resubmission.

[4] At CSE, we use the term "researcher," which is synonymous with "principal investigator."

D. Disapprove

1. The IRB shall disapprove the proposed research if it places the subjects at risks that outweigh the benefit or value of the knowledge to be gained, or it raises such serious ethical questions as to be unacceptable.

2. The IRB shall conduct a full review before disapproving a research project.

3. The IRB shall notify the researcher of the results of its action in writing.

6. Informed Consent

A. Definition

Informed consent is defined as a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research.

Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. **It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time.** Informed consent assures that prospective human subjects shall understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. This assurance protects all parties: both the subject, whose autonomy is respected, and the investigator, who otherwise may face legal hazards.

The process of informed consent is constituted by two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced, i.e., his or her consent is voluntary. Once informed consent is obtained, documentation to that effect shall follow the procedures outlined in this guide book.

Additionally, the researcher must be aware that litigation against the College and/or the researcher is always a possibility. From this perspective, even an ethical informed consent is not sufficient. The researcher needs to use an ethical informed consent that is legally valid.

A. General Requirements

1. The researcher shall use the following processes to obtain informed consent:

a. The researcher shall obtain consent from the subject or the subject's legally authorized representative.

b. The researcher shall obtain informed consent under circumstances that provide the subject with the opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.

c. The researcher shall ensure that the language in the Consent Form is understandable to the subject or his or her legal representative; where appropriate, the researcher shall have the Consent Form translated into a language(s) other than English and use acceptable translation methods.

2. The researcher shall ensure that the following content is included in a Consent Form[5]:

a. A statement that the study involves research;

b. An explanation of the purposes of the research;

c. A clear description of the procedures to be followed, including the duration of the subjects' participation in the study, in language that is understandable to the potential subject;

d. A description of any reasonably foreseeable risks or discomforts to the subject;

e. A description of any benefits to the subject or to others, which may reasonably be expected from the research;

f. A statement that participation is voluntary, that refusal to participate or withdraw involves no penalty, and that the subject may discontinue participation and have any data already collected destroyed at any time;

g. A statement describing the extent, if any, to which confidentiality of records identifying the subject shall be maintained;

h. An explanation of whom to contact if questions arise, including at a minimum, the name and telephone number of the Researcher and the Chair of the Institutional Review Board.

---

[5] Please use the appropriate Consent Form as posted on the website.

i. A statement that participation is voluntary, that refusal to participate or withdraw involves no penalty, and that the subject may discontinue participation and have any data already collected destroyed at any time;

j. For research involving more than minimal risk, an explanation as to whether and where any follow-up care is available; and

k. If relevant:

i. An identification of any procedures that are experimental;

ii. A description of circumstances under which the subject's participation may be terminated by the investigator without the subject's consent;

iii. A statement of who is responsible for any unforeseen additional costs to the subject resulting from participation in the research;

iv. A statement describing the extent, if any, to which confidentiality of records identifying the subject shall be maintained;

v. A statement that significant new findings developed during research that may relate to subject's willingness to continue shall be provided to the subject;

B. Exceptions from Requirements for Informed Consent

1. General Exceptions

The IRB may approve a consent procedure which does not include or which alters some or all of the elements of informed consent. Alternatively, the IRB may waive the requirement to obtain informed consent provided the IRB finds and documents one of the following conditions:

a. The research involves no more than minimal risks, shall not adversely affect the rights and welfare of subjects, and the research could not be practically carried out without a waiver or alteration. Whenever appropriate, the subjects shall be provided with additional pertinent information after participation.

OR

b. The research is to be conducted for the purpose of demonstrating or evaluating federal, state, or local service programs that are not research programs.

C. Assent Process for Minor Children

1. When minor children under age 18 are research subjects, the researcher shall obtain informed consent from the child's legal guardian for the child to participate in the research and for the researcher to contact the child.

2. When minor children are able to comprehend that they are being asked to participate in a research study, the researcher shall also obtain their assent, which is a statement attesting to the child's understanding and willingness to participate in the research.

D. Documentation of Compliance with Informed Consent Requirements

1. General Requirements

a. The researcher shall ensure that the subject or the subject's authorized representative signs the Consent Form.

b. The researcher shall retain the Consent Form in a secured file that is separate from the data collection instruments.

c. The researcher shall give a copy of the Consent Form to the subject or the subject's authorized representative.

d. The researcher may use a modified Consent Form for online surveys.

2. Exceptions to Documenting Informed Consent

a. The IRB may waive the requirement to obtain a signed Consent Form if:

i. The only record linking the subject and the research would be the Consent Form and the principal risk would be harm resulting from breach of confidentiality; and

ii. The research presents no more than minimal risk and involves no procedures for which written consent is normally required.

b. In cases where documentation is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

7. Special Populations

The federal government has extensively regulated and provided additional safeguards with respect to research, development, and related activities involving "special populations"; these include pregnant women, prisoners, and children.

A. Pregnant Women

1. General Requirements: The researcher shall comply with Protection of Human Subjects – Title 45, Code of Federal Regulations, Part 46, Office of Human Research Protection ().

B. Prisoners

1. General Statement

> Prisoners are members of a vulnerable class. The IRB requires more stringent procedural safeguards for this group because they are not entirely free to make decisions and choices as other adults in our society would be. As wards that are confined involuntarily by the government, prisoners are more prone to risks involving autonomy, privacy, loss of reputation, societal ostracism, criminal prosecution, civil liability, restrictions on freedom.

A study involving prisoners always requires IRB review and can never be considered exempt.

Prisoners are inmates in a locked facility, regardless of the institution (state prison, county jail, municipal jail, juvenile institutions, immigration detention center) and regardless of status (pre-trial, sentenced) People on parole or probation are not considered prisoners because they are not inmates; however, the IRB might still insist on a higher degree of protections as probationers and parolees (like prisoners) are serving a sentence imposed by the state and are being supervised by the state.

In some instances, research participants may begin their study participation as free people, but during the course of the study, they might become prisoners. In that event, they have become members of a vulnerable class, and the added protections must either be afforded them, or they must be dropped from the study.

Although prisoner participants require special consideration, the CSE IRB encourages members of the campus community to consider prisoner research. There are several important issues, such as effective treatment and staff training that have potential benefit

to improve conditions for prisoners and ultimately benefitting society. The CSE IRB is dedicated to facilitating high quality research on our campus.

2. General Requirements

a. A majority of the IRB (exclusive of prison members) shall have no association with the prison(s) involved, apart from their membership on the IRB.

b. At least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

c. Research funded by the US Department of Health and Human Services (DHHS) must follow all applicable regulations.

C. Children

1. General Requirements:

a. For research involving minimal risk, the researcher must obtain assent, if applicable, from the children and permission from the parents or guardians.

b. For research involving more than minimal risk, the researcher must comply with Protection of Human Subjects – Title 45, Code of Federal Regulations, Part 46, Office of Human Research Protection ().

2. Requirements for Parental/Guardian Permission and for Assent by Children

a. The IRB shall require that adequate provisions be made for soliciting the permission of each child's parents or guardians. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient if the research does not involve greater than minimal risk, or does involve greater than minimal risk, but may result in direct benefit to the individual subjects. If the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition, the IRB shall require both parents' permission. Exceptions would include: 1) one parent is deceased, unknown, incompetent, or not reasonably available, or 2) when one parent has legal responsibility for the care and custody of the child.

b. The IRB shall ensure that permission by parents or guardians is documented in accordance with and to the extent required under the Informed Consent section of this guidebook. The IRB provides two templates for Parent/Guardian Permission: a general form and one specific to focus groups, which includes a statement that the parent recognizes that it is expected that the child will not discuss what was said during the focus group outside of the meeting.

c. The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved or for each child, as the IRB deems appropriate. The IRB provides two templates for Parent/Guardian Permission: a general form and one specific to focus groups, which includes a statement that the parent recognizes that it is expected that the child will not discuss what was said during the focus group outside of the meeting. Researchers must use age-appropriate language and that my range from very simple language to working close or identical to that used for adults, depending on the developmental level of the child.

d. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research may be of direct benefit to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

e. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

3. Requirements for Children Who Are Wards (e.g., foster children)

Children who are wards of the state or any other agency, institution, or entity can be included in the research only under very specific conditions. Please contact the IRB for more information.

8. Adverse Events

A. Definition: Adverse events include both physical and psychological harms. They occur most frequently in the context of biomedical research, although on occasion, they may occur in social

and behavioral research. Since research involving human beings is a dynamic process, researchers may encounter situations where research participants experience unanticipated circumstances or situations that may cause harm. In such situations, the researcher must assess the seriousness of the situation and report an incident or outcome that meets all three of the following criteria to the IRB:

1. The incident or outcome posed a physical, psychological, economic, or social risk greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2. The incident or outcome was unanticipated given what subjects were told during the consent process and your knowledge of the study population;

3. The incident or outcome was related or possibly related to participation in the research ("Possibly related" means that the incident or outcome may have been caused by participation in the research).

B. As a condition of IRB approval, researchers must commit to reporting adverse events meeting the above three criteria within five business days to the IRB. The IRB posts a Reporting of Adverse Events form on its website for this purpose.