

FACULTY, STAFF, & STUDENT  
GUIDE TO

# RESEARCH WITH HUMAN SUBJECTS

PREPARED BY  
THE SIUE INSTITUTIONAL REVIEW BOARD

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The following forms can be found at  
[www.siu.edu/graduate/humansubjectsprotection](http://www.siu.edu/graduate/humansubjectsprotection)

**Form 1A -**  
Application for Approval of Projects Involving Human Research Subjects

**Form 1B -**  
Application for Approval of Projects Involving Human Research Subjects - Ethnographic Research

**Form 2 -**  
Instructions for The Preparation Of Your Acknowledgement of Informed Consent

**Form 3 -**  
Annual Review or Completion Report

**Form 4 -**  
Complaint Form

**Form - HIPAA Authorization Form**

**Form - Waiver of HIPAA Authorization Form**

## I. INTRODUCTION

Southern Illinois University Edwardsville (SIUE) is committed to the furthering of human understanding. Research is regarded as a major avenue leading to the advancement of such knowledge, especially when freedom of inquiry is available to investigators. Such freedom, however, must be earned through the conduct of research in a competent, moral, and responsible manner by investigators who not only hold to scientific values but also have the highest regard for the implications and consequences of their research on society and the individuals therein. At times, it is possible that the scientist's quest for knowledge may endanger the rights and welfare of individuals; guarding these rights must be a focus of constant concern and scrutiny. It is the investigator's responsibility to assess research procedures regularly to insure the protection of the individual and, when appropriate, to review them with associates and other responsible members of society.

With due regard for the freedom of inquiry, but with the highest regard for the safeguarding of individual rights and welfare, the following code and procedures are offered to serve as guidelines to be followed in this University for all research. This research includes that conducted by University faculty, staff, or students, on or off campus, whether funded or not. Non-SIUE personnel conducting research on the SIUE campus must also follow these guidelines. To be effective, such guidelines will have to be flexible enough to allow for changes in our value systems and for those modifications which necessarily will be required with experience.

## II. STRUCTURE OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The Institutional Review Board (IRB) is composed of at least five (5) members who are appointed by the Dean of the Graduate School. At least four of the members shall be on the faculty or staff of Southern Illinois University Edwardsville. These four appointees shall be selected in such a manner as (1) to insure that each has had experience in research with human subjects and (2) to provide as broad a base, in regard to academic/research specialties, as possible. The IRB membership shall conform to the federal rules and regulations concerning such membership constituency, including at least one member being a non-university employee. Board members shall serve indefinitely. The members of the IRB shall elect their own chairperson, who shall call and preside at all meetings of the Board. The Board shall meet bi-monthly or more frequently if determined necessary. The Signatory Official, the IRB Chairperson, and the Human Protections Administrator shall complete the mandatory Office for Human Research Protections (OHRP) on-line assurance training module upon filing the institutional Federal Wide Assurance (FWA) to OHRP. The Office of Research and Projects will provide the necessary educational training on human subjects protection in the form of workshops and on-line tutorials. The Expedited Review Board, composed of the IRB Chairperson, shall review all protocols as expeditiously as possible. The Chairperson may consult with other IRB members who have the expertise needed to facilitate the expedited review. The Human Subjects Administrator will help facilitate the process as requested by the IRB Chair. The IRB Chair will also determine if full board review is necessary.

The Board members shall be identified to the U.S. Department of Health and Human Services by name, earned degrees, if any, position or occupation, representative capacity, and by other pertinent indications of experience, sufficient to describe each member's chief anticipated contribution to Board deliberations. Any employment or other relationship between each member and the Institution shall be identified, i.e., full-time employee, part-time employee, member of governing panel or board, paid consultant, unpaid consultant. Also, changes in Board membership shall be reported to the DHHS in such form and at such times as the Human Protections Administrator may require.

The IRB is empowered to call in outside consultants and/or SIUE faculty consultants and may utilize review subcommittees where it deems appropriate.

**a. RESPONSIBILITIES**

**A. Responsibilities of the Investigator/Researcher**

While the Institutional Review Board (IRB) acts as the official review board, the investigator is not relieved of personal and ethical responsibility for the design and conduct of the research as it may affect the welfare of subjects involved. In addition to complying with the formal procedures for obtaining approval of a project by IRB, each investigator must:

- a. be thoroughly familiar with ethical guidelines for conduct of research utilizing human subjects and comply with these guidelines both in fact and spirit;

Research investigators and all supporting research staff are required to fulfill the education requirement for the protection of human subjects in research set forth by the U.S. Department of Health and Human Services (DHHS). This requirement may be fulfilled by completing the CITI Program computer based training on the protection of human subjects in research at:

[www.siue.edu/graduate/humansubjectsprotection/train\\_certify.shtml](http://www.siue.edu/graduate/humansubjectsprotection/train_certify.shtml).

2. be sensitive to ethical considerations related to his/her research which may not be specifically covered by the guidelines;
3. follow the established University procedures, along with those recommendations for alterations in procedure by the IRB which were given as part of the conditions of acceptance of the proposed project;
4. bring to the attention of the IRB any alterations in procedure which might conceivably have some relation to the rights or welfare of human subjects;

5. bring to the attention of the Board during any phase of any project problems (such as adverse reactions to drugs or medical devices) for further disposition by the Board and for reporting to the DHHS; and
  - a. submit an continuing review report or completion review report (Form 3) to the IRB.

If research is to be done with human subjects by a student under the auspices of the University, it is the responsibility of either the thesis or dissertation committee chairperson, or the faculty supervisor in the case of independent, class, or other study, to review the proposal and insure compliance with the IRB guidelines including fulfillment of the education requirement stated in No. 1.

If research is to be done in a classroom setting where students will be fulfilling a class assignment that requires research involving human subjects, it is the responsibility of the faculty member who is teaching the course to submit a classroom cover protocol to the IRB for approval. The faculty member is also responsible for the students' completion of the education requirement and must provide proof to the IRB that each student has completed that requirement.

**B. Responsibilities of the Office of Research and Projects (ORP)**

1. The Graduate School's Office of Research and Projects is responsible for determining if the research protocols qualify for exemption from continuing review under the common rule regulations 45 cfr 46.101. If exempt, the researcher will be notified in writing and no further reports are required except where changes in procedure arise. All nonexempt research protocols will be forwarded to the Expedited Review Committee of the IRB if they qualify for expedited review under the regulations, or to the full IRB if they do not so qualify.

2. All appeals of IRB decisions shall be submitted to the ORP for forwarding to the IRB for reconsideration.
3. The office will report information, as appropriate, to the IRB, the Office for Human Research Protections (OHRP), the Department of Health and Human Services (DHHS), research investigators and department heads.
4. Provide the means in which to educate each individual at the institution conducting or reviewing human subject research (e.g. faculty, staff, students) about the legal and ethical protection of human subject in research.

**C. Responsibilities of the IRB - Institutional Review Board**

Matters of choice of topic, research design, methodology, and controls are not of concern to the IRB except as they may bear upon the rights or welfare of the subjects involved or as they may clearly bear upon an assessment of the potential benefits to society in studies posing a definite risk to the subjects. The review responsibilities of the IRB are to:

1. meet as a Board with at least a quorum present and approve or disapprove with or without specified modifications the applications brought to it [A quorum of the Board shall be defined as a majority of the total membership duly convened to carry out the Board's responsibilities under the terms of the assurance.] As necessary, the Board will arrange to have qualified consultants with special competencies relevant to the proposal participate in the review. Approval shall be contingent upon assurance that the risks are kept to an absolute minimum and that any risks are clearly outweighed by the potential benefits. The Board may, at its discretion, invite the principal investigator (and the supervisor in the case of supervised research activities) to be present at the meeting so that

any modifications in procedure to protect subjects can be worked out directly between the Board and the investigator.];

2. offer consultation and advice on safeguarding the rights and welfare of human subjects;
3. review requests for exceptions or modifications to any University policy and procedures on research with human subjects;
4. collect continuing review reports and completion review reports for all projects involving human subjects to assure procedural compliance. EACH INVESTIGATOR MUST SUBMIT A CONTINUING REVIEW REPORT OR A COMPLETION REVIEW REPORT (FORM 3) ON AN ANNUAL BASIS AND AT THE COMPLETION OR TERMINATION OF THE PROJECT. These forms can be obtained on the Graduate School's website at:  
[www.siue.edu/graduate/humansubjectsprotection/irb.shtml](http://www.siue.edu/graduate/humansubjectsprotection/irb.shtml). If in the judgment of the Chairperson some problem may exist, the responsible investigator will be asked to appear before the Board for a comprehensive review.]; and
5. keep records and maintain a file of all projects reviewed for a period of at least three (3) years following completion of the project. All records shall be accessible for inspection and copying by authorized representatives of the federal government, or the IRB or ORP, at reasonable times and in a reasonable manner.
6. The SIUE IRB also serves as the Privacy Board for compliance issues related to the Health Insurance Portability and Accountability Act (HIPAA). The IRB will review protocols using individual protected health information (PHI) and assess the need for a HIPAA Authorization form or the waiver thereof.

#### **D. Appeals**

1. Researchers or investigators may appeal a decision of the IRB by presenting additional material to or requesting an appearance before the Board.

2. All appeals should be submitted in writing to the IRB in care of the Graduate School's Office of Research and Projects.

#### IV. DEFINITION OF TERMS

**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Classroom activities may also include research activities. Contact the Graduate School's Office of Research and Projects if you are not certain if your activity fits the *research* definition.

**Minimal Risk** means that 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.

A **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of

the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**Exempt** refers to various types of research (including some survey and ongoing educational research projects) which do not require continued monitoring by the IRB. Guided by the federal regulations, the Graduate School's Office of Research and Projects determines which projects fall into the Exempt classification.

**Informed Consent** means that except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. A minor under age 18 may refuse to participate in the research even if the minor's legally-authorized representative (parent or guardian) has given permission for the minor to participate. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative; in addition, minors must be informed about the research in language they can comprehend and asked if they want to participate in the research. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

***The Basic Elements of Informed Consent are:***

- a. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- b. a description of any reasonably foreseeable risks or discomforts to the subject;
- c. a description of any benefits to the subject or to others which may reasonably be expected from the research;
- d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- g. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- h. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

***Additional Elements of Informed Consent***

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- a. When required by the IRB, the research investigator shall provide one or more of the following additional elements of information to each subject, either orally or in writing as directed by the IRB:
- b. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- c. anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;
- d. any additional costs to the subject that may result from participation in the research;
- e. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- f. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- g. the approximate number of subjects involved in the study.

***Recommendations for Researchers***

Researchers are accountable for the quality of the informed consent protocol and for assessing comprehension of information for an informed consent. Accountability should take two forms: (a) researchers should incorporate empirically-based strategies that have been shown to increase comprehension and (b) researchers should assess research subjects' level of comprehension of information for an informed consent prior to admitting them into a study. If comprehension is inadequate, the researcher should make an effort to enhance the research subject's comprehension based on empirically effective strategies or, if impossible

to attain adequate comprehension, the researcher should exclude the subject from the study (or obtain a proxy).

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided that the IRB finds and documents that various conditions under the federal common rule regulations are met.

Researchers should consider the following:

1. present an amount of information for an informed consent that research subjects perceive to be the right amount for them;
2. present information clearly;
3. present any necessary anxiety-producing information (e.g., risks, complications, side effects) in as non-threatening a manner as possible;
4. present information simply -- ensure that level of difficulty of information in consent forms does not exceed research subjects' preferences or capabilities;
5. have the investigator, a nurse, or a health care team present (or follow up) information for an informed consent;
6. if possible, leave the informed consent form with research subjects so that they have adequate time to reflect upon it;
7. possibly use an audiovisual format to present information for an informed consent; and
8. actively involve research subjects in the processing of information for an informed consent.

## V. ETHICAL CONSIDERATIONS

## A. Protection of Individual Rights

1. Research should be conducted only by qualified investigators or by others only where a close supervisory relationship exists and is maintained with qualified individuals. Should an investigator become involved in areas which extend beyond his/her level of competence, appropriate consultation must be obtained.
2. Each research project must be evaluated in terms of its potential benefit to the subject and to society as well as in terms of its potential risk to the emotional and physical welfare of the subjects. Where risk is involved, or where information obtained is of a private nature, extra protection must be afforded the subject. Every effort should be made to minimize the risks or discomfort entailed in the subject's participation.
3. The investigator assumes responsibility for the procedures used throughout the course of the investigation. **IT IS THE INVESTIGATOR'S RESPONSIBILITY TO REPORT TO THE INSTITUTIONAL REVIEW BOARD (IRB) FOR PROJECT REVIEW ANY PLANNED CHANGES IN FORMAT OR PROCEDURES FROM THOSE ORIGINALLY APPROVED.** Should problems or harmful effects arise out of the experimental procedures, such responsibility would continue until the problem or effect is removed or until the subject is referred to an appropriate professional who has assumed responsibility for the subject.
4. Not only must the investigator take any immediate steps required to undo harmful effects, but if the study presents a potential to produce harm that may only manifest itself later, the investigator must initiate appropriate follow-up procedures to detect unpredicted harm.

5. The investigator must be sensitive to individual factors which may predispose certain individuals to experience enduring harmful psychological or physical consequences from participation in the study and to exclude such individuals from the research sample.
6. The investigator is obligated to keep the subject's data in confidence. This includes keeping the data in confidence from relatives, friends, employers, school officials, and from other professional associates of the investigator unless:
  - a. the subject or an authorized representative consents to disclosure, or
  - b. regulations of the Secretary of the Department of Health and Human Services so provide, or
  - c. as otherwise required by law.

It is the investigator's responsibility to report to the IRB how the data will be used and any subsequent changes in use.

7. Where information about private or personal matters is obtained from the subject for scientific purposes, the subject must be properly informed of how such information will be used, who will or might have occasion to examine such information, and how it might affect his/her future, including his/her civil rights. The subject must be advised that at any point he/she may withdraw from the experiment without penalty.
8. Where feasible, any private information obtained from a subject should be obtained anonymously or, if this is not possible, it should be immediately coded with care taken to keep the code separate from the data and in a secure place.
9. At the completion of the experiment, the investigator has the obligation to remove any misconceptions acquired by the subject, whether deliberately created or developed as an accidental by-product of the procedure.

10. Whenever possible, subjects should receive something of value for their participation. This benefit may be material (money, gifts, etc.) or educational (information, self-knowledge, etc.).
11. When the methodological requirements of research lead some subjects to experience failure or require the withholding of a potentially beneficial program or treatment from control subjects, the investigator must, insofar as possible, provide these subjects with a beneficial experience when the experiment is concluded.
12. It is unacceptable to intentionally cause a research subject to suffer embarrassment, fear, anxiety, or loss of self esteem. Such research may be justified only when:
  - a. the research objectives can be realized in no other way, and
  - b. the suffering of the research subject is limited in degree and duration to that minimum required to accomplish the research objectives.
13. An individual has the right to control any use of his/her person. Where a condition or circumstance exists which interferes with the right to freely control the use of his/her person, special precautions must be instituted to safeguard his/her rights and welfare.
14. It is incumbent upon the investigator to make sure that all subjects are treated with respect and dignity, and that the subjects are not imposed upon for the convenience of the researcher. Rather than adopting an ethical code, the University encourages researchers to follow the ethical codes established by their disciplines. Ethical codes or statements of principles established by the American Psychological Association, American Dental Association, American Sociological Association, and the World Medical Association will be referred to when appropriate to the conduct of the research.

**B. Appropriate Methods for Obtaining Consent****1. A SUBJECT'S PARTICIPATION IN RESEARCH SHOULD AT ALL TIMES BE**

**VOLUNTARY ON THE BASIS OF INFORMED CONSENT.** It is incumbent upon the investigator to provide the subject with all information about the study which is likely to bear upon the subject's willingness to participate. Conducting the proposed research in violation of this principle of informed consent may be justified only when all of the following conditions are met:

- a.** the risk to any subject is minimal;
- b.** the rights and welfare of any subject will not be adversely affected;
- c.** the research objectives cannot be realized without concealment;
- d.** any reasonable alternative means for attaining those objectives would be less advantageous to the subjects;
- e.** there is sufficient reason for concealment so that when the subject is later informed, he/she can be expected to find the concealment reasonable and suffer no serious loss of confidence in the integrity of the investigator or others involved in the situation;
- f.** the subject is allowed to withdraw his/her data from the study if he/she so wishes when the concealment is revealed to him/her before publication and/or publicity of data; and
- g.** the investigator takes full responsibility for detecting and removing stressful after-effects and, insofar as possible, for providing the subject with positive gain from the research experience.

**2. In recruiting subjects for research and obtaining their informed consent, the investigator must give potential subjects an honest**

description of the study without misrepresenting the purposes, procedures, benefits, or sponsorship of the research. Potential subjects should also be informed of the investment being asked of them, e.g., amount of time involved. Violations of this principle can be justified only under the conditions noted under B-1 above.

3. Where private information is sought or where risk may be involved, the subject should be fully informed regarding the nature of the information he/she will be asked to divulge and/or the possible risks, discomforts, or harm that he/she may undergo as a result of participating.
4. Where minors are used as the subjects for research outside of a school system or institution, only the parent or guardian shall give informed consent. In addition to this consent, children must have the research and informed consent information discussed with them so that they can understand these items and must be asked if they will participate in the research, thus providing their assent to participate in the research. Conditions noted under B-1 and B-2 also apply. Contact the Graduate School's Office of Research and Projects for information on obtaining implicit consent from the parent or guardian if signing the consent form presents difficulties. (For example, some researchers send letters home to the parents/guardians asking them to contact the school if they do **not** want their child[ren] to participate in the described research; if the parents/guardians do not contact the school, they are told that they have given their implicit consent for the child[ren] to participate in the research.)
5. In the circumstances that the research is conducted in an institutional setting, such as a school or hospital, where minors or committed patients are used as the subjects for research, informed consent should be secured both from the appropriate official and

from the parent or guardian if any, as well as assent from the children or patients. Conditions noted under B-1 and B-2 also apply.

6. In the circumstance of captives and/or dependents as found in institutions, prisons, hospitals, schools, etc., and relationships such as employer-employee, teacher-student, etc., where control is inherent in the circumstance, particular care is necessary to obtain informed consent using procedures that maximize the freedom of the subject to refuse participation. In the case of prisoners, the University will follow the Department of Health and Human Services regulations. Any value offered as a participation reward should not take advantage of any subject's deprived state. Conditions noted under B-1 and B-2 also apply.
7. Care must be taken that the subject's decision concerning participation is truly free and voluntary. To be avoided are:
  - a. being required to participate in research as a course requirement where no course-related pedagogical benefit can be justified,
  - b. direct or implicit suggestions that needed services (such as counseling, employment, housing) may be withheld or reduced if the subject refuses to participate in the research--it is the responsibility of the investigator to make clear to the subject that such services are not contingent upon participation,
  - c. pressure to participate because the subject's relationship to the investigator creates a situation where it is difficult to refuse (e.g., teacher-student, superior-subordinate relationships), and
  - d. pressure to participate put on subjects by arousing anxieties concerning personal shortcomings (e.g., cowardice,

defensiveness) or by the use of undue social influence or moral appeals.

8. Once involved in the study, the subject should still have the prerogative, at any time, to refuse to participate or to withdraw from an experiment, regardless of the reasons. Should he/she choose to exercise this prerogative, this right must be respected without obstruction or coercion by the investigator. An opportunity to discuss the reasons for withdrawal may be offered to the subject for the purpose of clarifying misunderstandings or reducing anxiety or other discomfort which may have been aroused by participation as a subject.

**C. Risks Versus Benefits**

1. All guidelines in PART A apply here.
2. Each research project must be evaluated in terms of the potential benefits to new knowledge, to society, and to the research subject as against the potential risks to the individuals involved. Where a proposed project involves substantial potential risks to subjects, the investigator:
  - a. has the responsibility to justify the possible benefits of the project, and
  - b. must be cognizant of previous research, both animal and human, done in the subject area.
3. Any project in which there exists a possibility of alteration or impairment of physical or psychological functions, of acute discomfort, or of emotional or social or other harm constitutes a risk. Such projects require special precautions and must follow approved procedures as set forth in Section VI, below, to obtain approval. Furthermore, any project which solicits private or confidential information as defined by the subject or qualified

person (or if this is not possible, by a parent, guardian, or other designated authority) must also be reviewed according to approved procedures under PART A.

#### **VI. STEPS FOR OBTAINING APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS**

1. All researchers and investigators whether faculty, staff, or students with research projects or activities involving the use of human subjects must submit an application for approval to the IRB, via the Graduate School's Office of Research and Projects.
2. Read the handbook entitled "Faculty, Staff, and Student Guide to Research with Human Subjects." Copies are available on the Graduate School's website at:  
[www.siue.edu/graduate/humansubjectsprotection/pdf/IRB\\_Manual.pdf](http://www.siue.edu/graduate/humansubjectsprotection/pdf/IRB_Manual.pdf).
3. Assemble the following materials:
  - a. a completed Application for Approval of Project Involving Human Research Subjects (Form 1) -- Part I is to be completed by the researcher. A copy of the research proposal may be requested by the IRB. The signatures in Parts I and II must be obtained.
  - b. a copy of all questionnaires or other research instruments (e.g. survey instruments, interview transcripts, advertisements, word puzzles, etc.);
  - c. a copy of the Acknowledgement of Informed Consent form (Form 2) that you plan to use along with a written summary of the information that will be given to subjects orally or in writing (e.g. the cover page that will accompany your informed consent form that will explain your research to the potential subject);
  - d. when the research involves the use of a vulnerable population such as children, the elderly, etc., a letter to the Chair of the IRB from an official of the institution where the research will be

conducted stating that the institution is aware of the research and approves of the research being conducted at that institution.

- e. a Registration of Thesis or Dissertation Title form (for master's and cooperative doctoral degree candidates). [Not required for candidates from other institutions.]
  - f. where protected health information is obtained for data collection, a HIPAA Authorization form or a Waiver of HIPAA Authorization form is required at the time of IRB review.
4. Bring or mail your application to the Graduate School's Office of Research and Projects, Rendleman 2202, Box 1046, SIUE, Edwardsville, IL 62026-1046.
  5. The researcher or investigator must not initiate the project until written notification is received that the application has been approved by the IRB. (Faculty supervisors will receive such notification when the researcher is an SIUE student.)

***ALL INFORMED CONSENT FORMS MUST BE SUBMITTED TO THE IRB FOR APPROVAL. THE INFORMED CONSENT FORM MUST COVER ALL POINTS LISTED IN THE BASIC ELEMENTS OF INFORMED CONSENT AND, WHERE APPROPRIATE, ADDITIONAL ELEMENTS OF INFORMED CONSENT. (See page 10 of this handbook)***

**NOTE:**

The expedited review committee can generally meet to approve most protocols within four weeks of submission. The IRB shall meet as frequently as is determined necessary to review applications for approval that cannot be granted by the expedited committee. You (or the faculty supervisor for SIUE students) will receive written notification of approval or disapproval and, if approval is granted, the IRB's decision regarding the form and extent of documentation of informed consent.

If you need assistance with your application or have any questions

concerning the review process, please contact Linda Skelton in the Graduate School's Office of Research and Projects at [lskelto@siue.edu](mailto:lskelto@siue.edu) or 618-650-2958.