

SIUE HUMAN SUBJECTS HANDBOOK

**FACULTY, STAFF, & STUDENT
GUIDE TO**

RESEARCH WITH HUMAN SUBJECTS

PREPARED BY
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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: <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>. 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 BOARDS

Southern Illinois University Edwardsville (SIUE) Institutional Review Board (IRB) membership shall conform to the federal rules and regulations concerning such membership constituency as follows: The SIUE IRB is composed of at least five members who are appointed by the Associate Provost for Research and Dean of the Graduate School (APR). This includes at least one member from the community who is not affiliated with SIUE, and at least four of the members shall be on the faculty or staff of SIUE. These four appointees shall be selected in such a manner as (1) to insure each has had experience in research with human subjects, (2) to provide as broad a base, in regard to academic/research specialties, as possible and (3) one member who is a non-scientist. (In order to have a quorum at convened meetings, the community member may substitute for the non-scientist if the community member is a non-scientist and if the non-scientist faculty member is not available). Board members shall serve a 3-year term which is subject to renewal. The IRB shall meet once a month, if needed, and more frequently if determined necessary. Office of Research and Projects (ORP) will provide the necessary educational training on human subject's protection via the use of the Collaborative Institutional Training Initiative (CITI) Program. Under an expedited review procedure, the IRB Chair- or the IRB Co-Chair-, and/or one or more experienced reviewers designated by the Chair- or Co-Chair- from among the members of the IRB, reviews the research protocol. The Human Subjects Administrator(s) will help facilitate the process as requested by the IRB Chair or Co-Chair. The IRB Chair or IRB Co-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 Subjects Administrator(s) 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.

III. 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:

- 1) 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 online computer- based training program available on the SIUE IRB website;
- 2) be sensitive to ethical considerations related to his/her research which may not be specifically covered by the guidelines;
- 3) provide an honest and thorough description of their research to the IRB via the Kuali electronic protocol system. It is the responsibility of the researcher to make sure the IRB has all components necessary to conduct an informed review (e.g. speak in lay language when discussing their research; provide adequate informed consent; provide proof of human subject's protections training; copies of flyer, surveys, interview questions, letters of support; etc.).
- 4) 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;
- 5) 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;
- 6) bring to the attention of the Board during any phase of the project any unanticipated problems or adverse reactions (such as emotional effects, and adverse reactions to drugs or medical devices) for further disposition by the Board and for reporting to the DHHS; and 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 adviser 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 protocol to the IRB for approval. The faculty member is also responsible for the students' completion of the education requirement.

- 7) allow enough time in their research plan for IRB review. Review time-lines are a responsibility of not only the IRB, but also of the researcher. Not only should researchers submit to the IRB long before they plan to begin their research, they should also build in time for back and forth revision requests/returns.

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

- 1) The Human Subjects Administrator(s) in the Graduate School's Office of Research and Projects are responsible for determining if research protocols qualify for exemption from further review under the common rule regulations 45 CFR 46.104. If exempt, the researcher will be notified in writing and no further reports are required except where changes in procedure arise. All non-exempt 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 of Research and Projects 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) The Office of Research and Projects will 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 full board projects, and any expedited project deemed by the IRB to require reports, involving human subjects to assure procedural compliance. 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: Per 45 CFR 46.102 Revised Common Rule 2018 Requirements

(a) **Certification** means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(b) **Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

(c) **Department or agency head** means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

(d) **Federal department or agency** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to

make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.*, the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

(e)(1) **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) *Intervention* includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) *Interaction* includes communication or interpersonal contact between investigator and subject.

(4) *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.*, a medical record).

(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(7) Federal departments or agencies implementing this policy shall:

(i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of “identifiable private information,” as defined in paragraph (e)(5) of this section, and “identifiable biospecimen,” as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate “identifiable private information,” as defined in paragraph (e)(5) of this section, or an “identifiable biospecimen,” as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the FEDERAL REGISTER after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

(f) **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies).

(g) **IRB** means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) **Legally authorized representative** means 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 research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(j) **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.

(k) **Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(l) **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed NOT to be research:

(1) Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(m) **Written, or in writing**, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

V. Requirements for Informed Consent.

(a) General Requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized 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.

(b) Basic Elements of Informed Consent. Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) 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 that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) 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;

(7) 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;

(8) 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; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) Additional Elements of Informed Consent. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) 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) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- (6) The approximate number of subjects involved in the study;
- (7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- (9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

- (1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;
- (2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
- (3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
- (4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
- (5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials—(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(A) Public benefit or service programs;

(B) Procedures for obtaining benefits or services under those programs;

(C) Possible changes in or alternatives to those programs or procedures; or

(D) Possible changes in methods or levels of payment for benefits or services under those programs; and

(ii) The research could not practicably be carried out without the waiver or alteration.

(f) General waiver or alteration of consent—(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the

requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) Screening, recruiting, or determining eligibility. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(h) Posting of clinical trial consent form. (1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

(i) Preemption. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(j) *Emergency medical care.* Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

(k) *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.

VI. 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 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 confidential. This includes keeping the data in confidence from relatives, friends, employers, school officials, and from other professional associates of the investigator unless:
 - i. the subject or an authorized representative consent's to disclosure, or
 - ii. regulations of the Secretary of the Department of Health and Human Services so provide, or
 - iii. 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:
 - i. the research objectives can be realized in no other way, and

- ii. 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 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 written assent to participate in the research. Conditions noted under B-1 and B-2 also apply. The IRB will NOT approve the practice of obtaining implicit consent from the parent or guardian.

- 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 in the form of a letter of support, 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 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 vs 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.

VII. STEPS FOR OBTAINING IRB APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

All faculty, staff, or students conducting research involving the use of human subjects must submit a protocol to the IRB, via the Graduate School's Office of Research and Projects Quali electronic protocol system. (See instructions on how to access and complete an IRB Protocol in the Appendix of this Handbook ((Appendix I)).

- 1) Complete the required online training for research involving the use of human subjects via the CITI Program online training course(s) at: www.citiprogram.org. (See instructions on how to complete the correct training course in the Appendix of this Handbook ((Appendix II)).
- 2) Read this handbook entitled "Faculty, Staff, and Student Guide to Research with Human Subjects." Copies are available on the Graduate School's website at: <http://www.siue.edu/compliance/human-subjects/related-resources.shtml>
- 3) Include as attachments to the electronic protocol the following materials:
 - a. a copy of all questionnaires or other research instruments (e.g. survey instruments, interview transcripts, data collection document(s), advertisements, word puzzles, etc.);
 - b. a copy of the following consent documents, as they apply to your research, using the SIUE IRB template provide at: <http://www.siue.edu/graduate/funding-compliance-forms.shtml>
 - c. the Informed Consent for Subjects Over 18 form (for non-exempt review)
 - d. the Informed Consent for Subjects Under 18 form (for non-exempt review)
 - e. the Informed Consent for Scholarship of Teaching and Learning form (for non-exempt review)
 - f. the Recruitment Document & the Research Participant Notification form (for exempt reviews)
 - g. a copy of the Child Assent form (for research involving children between the ages of 8 and 17)
 - h. a copy of the Audio/Video Recording Release Consent Form
 - i. a letter of support when the research involves children. The letter of support should be written to the Chair of the IRB from an official of that institution where the research will be conducted, on official letterhead, stating that the institution is aware of the research and approves of the research being conducted at that institution is required.
 - j. a HIPAA Authorization form or a Waiver of HIPAA Authorization form where protected health information is accessed or obtained for data collection.
- 4) IRB approval must be obtained BEFORE any aspects of the research can begin, including participant recruitment and data collection.

ALL INFORMED CONSENT FORMS, ASSENT FORMS, AUDIO/VIDEO FORM MUST BE SUBMITTED TO THE IRB FOR APPROVAL. THE IRB APPROVED STAMPED FORMS MUST BE USED AND MUST NOT BE MODIFIED UNLESS THOSE MODIFICATIONS HAVE BEEN APPROVED BY THE IRB. THE INFORMED CONSENT FORM MUST COVER ALL POINTS LISTED IN THE BASIC ELEMENTS OF INFORMED CONSENT AND, WHERE APPROPRIATE, ADDITIONAL ELEMENTS OF INFORMED CONSENT.

NOTE: You and/or the faculty supervisor for SIUE students will receive 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 IRB review process, please contact the Research Compliance Coordinator in the Graduate School's Office of Research and Projects at irbtraining@siue.edu or 618-650-3010.

APPENDIX: Appendix I: How to access and complete an IRB Protocol for research involving the use of human subjects.

VIII Protocol Submission Instructions:

(watch the online tutorial called “Protocol: Human Subjects Research” for a guide on using the Kualii protocol system by going to: <http://www.siu.edu/funding/external-funding/kualii-research.shtml>)

1. To begin the protocol process, go to: <https://siue.kualii.co/protocols/> and login with your SIUE e-id and password.
2. On the left-hand side of the page, click on “Manage Protocols,” then, on the top right side of the screen, click “+ New Protocol” and then click on “IRB.”
3. Please fill out the protocol completely.
4. If you are a student, be sure to add your faculty advisor’s information to the “People” section of the protocol and attach the signed “Student Project Faculty Adviser Certification” form. (A link to this form is provided just below the “Attachment” section of the protocol.

Attachment Instructions:

1. Links to most of the forms you may need to attach (e.g. Informed Consent, Child Assent, Recruitment Documents, Student certification form, etc.) can be found just below the “Attachment” section of the protocol.
2. Be sure to attach all required documents to the protocol before submission so your protocol can be reviewed in a timely manner.
3. The CITI certificate of training completion must be attached to the protocol before submission. if you see your certificate listed in the “CITI Certificate” column in the “People” section, you do not have to upload your certificate. If it is NOT there, you will need to upload a copy into the “People” section.

CITI IRB Training Instructions for Research with Human Subjects:

To complete a training course(s) in the CITI System, please follow these instructions:

Go to www.citiprogram.org.

Click on “Log In”

1. Then, at the top of the page, click on “Log In Through My Institution.” (If you have already log in before, depending on your browser, you may be taken directly to signing in with your e-id and password, if so, proceed to #5 below.)
2. Choose Southern Illinois University Edwardsville from the drop-down box.
3. You will be taken to the SIUE single sign-on page where you will enter your SIUE e-id and password, then click “LOGIN” just below.

4. At the top left side of the page you should see “Welcome, [and your name].” In the middle of the page, under “Institutional Courses,” Click on the “View Course” button.
5. You should now see a list of “Active Courses” and Southern Illinois University Edwardsville at the top. From this list of courses, choose one or more of the following:
 - **“IRB Social Behavioral Student”**
 - **“IRB Social Behavioral Faculty”**
 - **“Biomedical Researcher.”**

IMPORTANT: IF those courses are not listed, scroll all the way down to the bottom of the page and click on “Add a Course.” Then scroll down until you see a series of questions relating to other courses (go ahead and answer all questions as they relate to you.)

7. After answering these questions, scroll to the bottom of the page and click **“submit.”** It will take you back to the “Active Courses” page where the correct course(s) should now be listed.
8. You are now ready to complete the course(s). Once completed, the CITI system will provide you with a Certificate of Completion for each course. You may print and/or save a copy for your records.

CITI certification is good for 3 years for human subject’s research.

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