SIU CARBONDALE
SOUTHERN ILLINOIS UNIVERSITY
OFFICE OF SPONSORED PROJECTS ADMINISTRATION

Human Subjects Protection: A Guide for Researchers

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Section 1: Preface

The Human Subjects Committee (HSC) is the Institutional Review Board for Southern Illinois University Carbondale (SIUC). The HSC has the responsibility for reviewing all non-medical research involving humans as subjects that is conducted by faculty, students, or other employees of SIUC. This Guide was prepared to help researchers submit applications to the Committee for their review. It discusses principles and policies related to the use of human subjects in research, and common problems that researchers encounter in their interactions with the Committee.

Section 2: Fundamental Principles for Use of Human Subjects in Research

2.1 Belmont Principles

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The report sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those basic principles are respect for persons, beneficence, and justice.

Respect for persons recognizes the personal dignity and autonomy of individuals, and requires special protection of those persons with diminished autonomy, e.g., children, people in human service settings, prisoners. Researchers must get full consent from individuals before conducting research. Consent involves informing them about the research procedures, the purpose of the research, and the risks and anticipated benefits. Subjects must be given a chance to ask questions and to withdraw from the research at any time. To ensure that consent is truly voluntary, researchers should not coerce or use undue influence to get subjects to participate.

Beneficence entails an obligation to protect persons from harm by maximizing benefits and minimizing possible risks. The appropriateness of involving vulnerable populations must be demonstrated, and the consent process must thoroughly and completely disclose relevant risks and benefits.

Justice requires that the benefits and burdens of research be distributed fairly. Researchers should not select subjects simply because they are readily available or because they are vulnerable based on illness, age, or socioeconomic condition. Research should not overburden individuals who are already burdened by their environments or their conditions.

2.2 Federal Regulations

The federal government regulates research with human subjects. The Code of Federal Regulations (45 CFR 46) incorporates the ethical principles described in the Belmont Report and provides basic guidelines for the HSC.

2.3 University Policy on Human Subjects

SIUC is guided by the ethical principles set forth in the Belmont Report and by the requirements of the Code of Federal Regulations (45 CFR 46). Approval for conducting research with human subjects must be obtained from the HSC prior to the recruitment and any involvement of subjects. The HSC will periodically re-evaluate the project until it is completed. SIUC has a Federal-wide Assurance (FWA) for the Protection of Human Subjects, a contract with the federal government assuring that SIUC will review all human subject research conducted by any person affiliated with SIUC.

All SIUC researchers must follow the policies outlined in this Guide when they are conducting research that involves humans, regardless of whether the research is externally funded or not. The human subjects policy and review process applies to pilot projects, students' theses and dissertations, surveys, faculty projects, independent study projects, and all other research with human subjects.

The HSC reviews all research that involves human subjects if one or more of the following apply:

- The research is sponsored by this institution, or
- The research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or
- The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
- The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

If a researcher from a non-SIUC institution wishes to conduct research using SIUC staff or students as the subject pool and none of the above conditions apply, the HSC may require evidence from the researcher that IRB approval was obtained from his/her institution.

2.3.1 Research Conducted Cooperatively with Another Institution

When researchers from more than one institution with a Federal-Wide Assurance (FWA) are involved in research, each institution is responsible for safeguarding the rights and welfare of human subjects and federal regulations compliance. One institution may delegate the other to act as the IRB of record by a written IRB Authorization Agreement. It is the responsibility of the investigator to seek his/her IRB counsel prior to engaging in

research with an investigator at another institution. If an investigator's IRB chooses to delegate to another institution, the FWA must be amended per OHRP regulations.

2.4 Noncompliance by Researchers

Researchers are responsible for complying with all HSC decisions and requirements. Failure to comply with the HSC findings is serious and can, in the worst case, result in the University losing the right to conduct any research involving human subjects. The HSC cannot and will not review protocols for projects that are already in progress or that have been completed.

Sometimes a researcher will totally ignore or avoid the HSC. These problems create difficulties for the subjects, the HSC, and SIUC. When the HSC discovers that someone affiliated with SIUC is involved in unapproved research with human subjects, the HSC and SIUC will act promptly to halt the research. Students and faculty risk the loss of data for their research if those data were gathered before obtaining approval from the HSC. The Graduate School will not accept theses or dissertations if the research involved human subjects and was not approved by the HSC prior to the data being gathered. Any serious noncompliance with our assurance statement must be reported to the Office for Human Research Protections, the federal agency at DHHS that oversees research with human subjects.

Section 3: Definitions

3.1 Research

For the purposes of the HSC and federal regulations, the term **research** refers to any systematic gathering and analysis of information designed to develop or contribute to *generalizable* knowledge. Although the following list is not exhaustive, research includes:

- Any interviews, surveys, tests, or observations that are designed to gather nonpublic information about individuals or groups.
- Studies of existing data, either public or private, where the identity of individuals is known.
- Studies designed to change subjects' physical or psychological states or environments.

The purpose of gathering the data is one way to determine whether the project is generalizable. If the researcher intends to publish the results or present the information at a public meeting, the project is designed to contribute to a wider audience and is, therefore, generalizable. Using this definition of research, some demonstration and service programs may include research activities.

Most internal program evaluations to determine student/audience satisfaction or knowledge gained during a routine program activity do not meet the federal definitions of research. If the evaluators' intention is to publish the results of the evaluation, that changes the evaluation to generalizable knowledge, and the HSC must review the project. Results from program evaluations may not be published unless the HSC has approved the project prior to the data being gathered. (See Common Problem Areas VI, F for further discussion.)

3.2 Human Subjects

Human subjects are living individuals about whom an investigator obtains (a) data by intervention or interaction with the individual, or (b) identifiable private information. The private information may include the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

3.3 Intervention

Intervention includes physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

3.4 Interaction

Interaction includes communication or interpersonal contact between investigator and subject.

3.5 Private Information

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 which the individual can reasonably expect will not be made public.

3.6 Minimal Risk

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. Minimal risk is affected by the context of the research, including characteristics of the subjects.

3.7 Responsible Project Director

Responsible project director means a qualified faculty or staff member who will monitor the project involving human subjects. If a student is conducting the project, a qualified faculty or staff member must supervise the research. The student and the faculty or staff member must sign the HSC application, signifying that the student's work will be supervised and will conform to University and federal guidelines.

Section 4: Distribution of Responsibility

4.1 Researchers

The individuals responsible for conducting or supervising the research have the primary responsibility for protecting the rights of human subjects. Responsible project directors who supervise student research projects, including theses and dissertations, accept responsibility for the work that is done under their direction and ensure that students comply with the letter and the spirit of the HSC policies.

Modifications: If any changes need to be made in a protocol, the researcher will submit a written request to the HSC describing the modifications. No change in procedures may be made without prior written approval from the HSC. If the modification requires a new consent form or survey questions, the researcher must submit the new forms with the changes highlighted or in bold type. These modifications will be reviewed at the appropriate level. If the changes are minor, only one person will need to review it; if the changes are extensive or if the initial review was a Category III review (see below), it may have to be reviewed by the full committee.

Consent forms: The researcher will provide a copy of the HSC-approved consent form to each subject or guardian at the time of consent, unless the HSC has specifically waived this requirement. The researcher will retain signed consent forms in a secure location separate from the data for at least **three years** after the completion of the research.

Adverse events: Adverse events include unanticipated side effects or any injuries sustained as a result of the research. The researcher will immediately report all adverse events to the Chair of the HSC at (618) 453-4533 **and** to the Director of OSPA at (618) 453-4531.

Continuation reviews: The length of the approval will be determined by the HSC but cannot exceed one year. If the research is not completed within the allotted time, the researcher must request an extension to continue the research. Extension forms are available from the HSC secretary at Woody Hall C-214, (618) 453-4533.

4.2 Human Subjects Committee

The HSC at SIUC is an administrative body established to protect the rights and welfare of human research subjects. The HSC is authorized to review, approve, require modifications in, and disapprove all research projects with human subjects that are within SIUC's jurisdiction as specified by federal and institutional policies. Federal regulations are the minimum standards. The HSC consists of a minimum of five voting members with diverse backgrounds to provide complete and adequate review of human research and its institutional, legal, scientific and social implications. Local HSCs have the flexibility and empowerment to employ standards that the committees deem necessary for each protocol.

The HSC members are appointed by and report to the SIUC Vice Chancellor for Research. The HSC functions independently of other University committees. It makes an independent determination whether to approve or disapprove the protocols based upon

whether the subjects are adequately protected from risk. Research that has been reviewed by the HSC may have to be reviewed by other officials at the University, and these officials may disapprove the research. For example, University officials may not approve the researcher requesting access to a specific population, despite the HSC having reviewed and approved the project. No official at SIUC may approve any research project with human subjects that has been disapproved by the HSC. (45 CFR 46.112)

Section 5: Review Procedures

There are three application forms for human-subjects research at SIUC; submit the one appropriate to your project:

- Standard application
- Application for oral-history/field research (see section 7.4)
- Application for research using existing or secondary data (see section 7.6)

These forms are fillable Microsoft Word files. NOTE: The completed application cannot be submitted electronically. Mail it to OSPA, MC #4709, or bring it to Woody C-214.

The HSC Secretary initially examines all applications to the HSC for completeness. The Secretary will send all proposals to either the HSC Chair or Administrator. The Chair or the Administrator of the HSC will review all proposals and make the final determination as to the level of review that will be needed for each proposal. The Secretary maintains a database and a hard copy file for each project, including all correspondence between the researchers and the HSC. After a project has been approved and the work begun, the researcher must file a request to continue the research as indicated by the HSC, but at least once a year.

SIUC has three levels of review, Category I, Category II, and Category III, based on the potential risk to the human subjects.

5.1 Category I

Under federal regulations certain types of research are exempt from review unless the institution chooses to review it. According to SIUC policy, all research with human subjects will be reviewed and must be approved prior to the gathering of any data, including those projects that fall within the federal "exempt" category. These projects involve little risk beyond that which a person encounters in daily life. Either the Chair or the Administrator will review the Category I proposals.

Research activities in which the only involvement of human subjects will be in one or more of the following areas will be reviewed as Category I applications.

(A) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(B) Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified, either directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(C) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

(D) Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (2) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

5.2 Category II -- Expedited Review -- 45 CFR 46.110

If proposals meet certain criteria that are clearly defined in the federal guidelines, a subcommittee of the HSC may review the proposals as a Category II or Expedited proposal. The subcommittee reviewers consist of the Chair and the Administrator of the HSC or their designee. The detailed guidelines for Category II review are as follows.

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the HSC through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) HSCs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or

convened—used by the HSC.

(F) Categories one (1) through seven (7) pertain to both initial and continuing HSC review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application is not required.
    b. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
    b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
    a. Hair and nail clippings in a nondisfiguring manner.
    b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction.
    c. Permanent teeth if routine patient care indicates a need for extraction.
    d. Excreta and external secretions (including sweat).
    e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue.
    f. Placenta removed at delivery.
    g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
    h. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accORDAnce with accepted prophylactic techniques.
    i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
    j. Sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
b. Weighing or testing sensory acuity.
c. Magnetic resonance imaging.
d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
8. Continuing review of research previously approved by the convened HSC as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; **or**
    b. where no subjects have been enrolled and no additional risks have been identified; **or**
    c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories two (2) through eight (8) do not apply but the HSC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

5.3 Category III -- Full Committee Review

Research proposals that do not meet the criteria for a Category I or II will be reviewed by the full HSC. By definition, proposals that require a Category III level of review present more risk to subjects than do the other two levels of review. The full committee will review Category III proposals at a regularly convened meeting. The full HSC meets once a month, usually on the first Friday of the month.

Section 6: Obtaining Informed Consent

Informed consent is one of the primary ethical requirements of involving humans in any research activity. It assures that participants understand the research and what they will be expected to do so that they can make an informed decision about whether they want to participate in it. Informed consent reflects the basic principle of respect for persons.

It is essential that researchers think of informed consent as an educational process that takes place between the investigator and the prospective subject, and not just as a form that must be signed. No one can guarantee that another person has understood the information presented; one must inform prospective subjects as clearly as possible. The researcher also must ensure that subjects understand all information that is presented. In some cases, it may be necessary to ask the subjects to explain the research procedures to verify their understanding.

6.1 Basic Elements of Informed Consent

The federal regulations require that certain information must be provided to each subject [Federal Policy §46.116(a)]:

1. A statement that the study involves research, an explanation of the purposes of the research, 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 reasonably may 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 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, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The regulations further provide that the following additional information be provided to subjects, where appropriate [45 CFR 46.116(b)]:

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 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 be related to the subject's willingness to continue participation will be provided to the subject, and
6. The approximate number of subjects involved in the study. Investigators may seek consent only under circumstances that (a) provide the prospective subjects or their representative sufficient opportunity to consider whether or not to participate, and (b) that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the subject or representative. The consent process may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence [45 CFR 46.116].

6.2 Use of Data: Anonymous versus Confidential

In the consent form, researchers should explain clearly how they will use the collected data and how it will be handled. The most secure procedure is not to ask for names or any other identifying information—to keep the identity of the subjects completely anonymous. Only those studies that do not ask for names or any easily identifiable information may be described as anonymous. Anonymity means that the researcher cannot link the data to individually identifiable subjects.

Although anonymity may be useful for some studies, it is not practical for others. In studies that are not anonymous, subjects' data should be confidential. A coding procedure should be used in which each subject's identifying name or number is linked to a code number. The code number should be used on all data. A list linking the identifier to the code number should be kept secure, and a limited number of people should have access to the list. Researchers must tell subjects who will have access to the code list and what will happen to it upon completion of the study. When data are not anonymous, consent forms should include a statement such as, "We will take all reasonable steps to protect your identity." Researchers should not *promise* that they will maintain confidentiality, because any data could be obtained by court order.

6.3 Additional Requirements for Specific Research Methods/Populations

Some research methods and some populations of research studies create unusual problems in obtaining informed consent. To ensure that participants understand the risks and requirements of various research methods, the HSC has adopted some guidelines for these specific methods and populations.

6.3.1 Audio/Videotaping

If participants are to be audio/videotaped, there are several additional requirements to safeguard the privacy and confidentiality of the data. Explicit consent must be obtained for any public use of the tapes, such as use in the classroom or as part of a public presentation of the research results. This constitutes a waiver of the normal confidentiality of research data.

In the consent form, researchers should:

- Include a statement describing the recording procedures.
- Indicate how confidentiality will be maintained.
- Include a statement similar to, "I agree to participate in this activity and know that my responses will be recorded on audio/videotape."
- Describe how the tapes will be stored, who will be allowed to hear/view the tapes, and when or if the tapes will be erased. If the tapes will **not** be erased, you must get the participants' written permission to keep the tapes and tell them where the tapes will be kept, who will view the tapes, and how the tapes will be used in the future (e.g., future research, valuable historical data.)

Each participant must sign the consent form, indicating approval for the taping. If taping is planned in a group setting, the consent of **all** members of the group must be obtained for taping to take place.

Sometimes recordings are made with participants who are willing to be a research subject, but are reluctant to sign a consent form. Federal regulations allow the HSC to waive signed consent forms, and the researcher may obtain verbal consent on the tape. Participants must be informed of their rights, confidentiality, and all other aspects of consent. The researcher must provide a written script of the verbal consent process to the HSC.

6.3.2 Incentives

Researchers should not offer students or employees any academic or professional advantage over others who do not volunteer, nor should they pose any penalty to those who choose not to volunteer. (See Dual Relationships: Students, Clients, and Employees as Subjects, VI. A)

If students are offered extra-credit course points for volunteering, those who do not volunteer must be offered alternatives to earn the same number of extra-credit points; the alternatives must require an equal time and effort commitment. For example, completing a research questionnaire that takes thirty minutes is not comparable to writing a two-page critical review of a journal article. Incentives should be compensatory to time and effort that subjects invest in the research, and not so substantial that they constitute coercion to participate.

Individuals who accept money for participation in research projects paid by University

accounts should be informed that their confidentiality may be compromised because of reporting requirements at Southern Illinois University and the IRS.

6.3.3 Possible Physical Harm

Describe any physical risks to the subject that might arise from participating in the research and the steps you will take to minimize those risks. When visual or auditory stimuli, chemical substances, or other measures might affect the health of subjects, the researcher must provide the HSC with a statement from a person qualified to evaluate risks for such conditions.

In some cases, subjects should be told that a medical questionnaire must be completed, and that they may be excluded from participation based on their responses.

The following paragraph should be included in the consent form:

"The Department of Health and Human Services requires that you be advised as to the availability of medical treatment if a physical injury should result from research procedures. The researchers do not have funds specifically dedicated to compensate you for any adverse effects that you may experience by participating in this research. Nevertheless, you retain all your legal rights to seek compensation in the event of injury or other adverse event. If you are a registered student at SIUC, you are eligible to receive medical treatment at Student Health Center. If you are not a registered student at the University, immediate medical treatment is available at usual and customary fees at Memorial Hospital of Carbondale. In the event you believe you have suffered any injury as a result of participating in the research program, please contact the Chair of the Human Subjects Committee, who will review the matter with you. Phone (618) 453-4533."

6.3.4 Drawing Blood

If blood is to be withdrawn, include a statement in the consent form indicating the amount of blood to be withdrawn and potential complications, including possible bruising, inflammation, and infection at the site of the puncture. Name the individual who will withdraw the blood, state his/her qualifications, and assure subjects that care will be taken to avoid any complications.

All applications that include blood drawing must include verification that the people drawing blood are qualified to do so. This verification should be from SIUC's Center for Environmental Health and Safety, (618) 453-7180.

6.3.5 Deception

All other possible research strategies should be explored before settling on a deceptive approach to research. Intentionally misleading or providing misinformation to participants is not usually a desirable procedure. It exploits the participants' vulnerability and

interferes with their ability to give informed consent. If deception is the only way that important research can be done, the researcher must explain to the HSC all steps that will be taken to protect the participants from psychological and physical harm. The missing or misleading information must not put the participants at risk.

Researchers may inform the participants that the study involves deception without revealing critical information about the study. For example, a possible quote to use is, "We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these circumstances, we will explain the procedure to you fully after your participation."

When deception is used, thorough debriefing of the participants is essential. A debriefing statement, which must be approved by the HSC, should describe the deception, the purpose of withholding information, the reason for the study design, and help the participant address any distress brought on by the research. Participants must be given the opportunity to withdraw their data at the time of debriefing if they object to the deception. This procedure will allow participants to decide if they continue to agree with the aims of the study and the inclusion of their data in it.

6.3.6 Children

There are special requirements in the consent process when children participate in research projects. The legal age for consent to treatments or procedures involved in research depends on the applicable law of the jurisdiction in which the research will be conducted. (In Illinois, persons under the age of 18 are considered children/minors.)

Permission of Parents or Guardians

Parents or guardians must give written permission before their child can participate in a research project. All of the elements of informed consent should be included in the parental consent form, including a detailed description of what the child will be asked to do and, in the case of surveys, samples of the questions that are on the survey.

If the research with children occurs in a school setting, the HSC may waive parental consent if the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. Please note that only the HSC may waive parental consent. For more details, see section 6.3.8, "Research in Schools and Human Service Organizations (Action Research)."

Wards of State

If children are wards of the state, there are special provisions that must be met. The research must be (1) related to their status as wards; or (2) conducted in schools, camps, hospitals, institutions, or similar setting is which the majority of children involved as subjects are not wards. If the research meets one of the above criteria, the HSC shall require appointment of an advocate of each child who is a ward, in addition to any other individual acting on behalf of the child as guardian. [45 CFR 46.409]

Assent of Children

"Assent" means a child's affirmative agreement to participate in research. The researcher should solicit the assent of children if the children are capable of assenting. To determine whether the child is able to assent, the researcher and the HSC will take into account the child's age, cognitive level, and psychological state.

If the child can give assent, the researcher will prepare a script describing to the child what he/she is being asked to do. This script will be in language appropriate for the child's cognitive level. The researcher will describe to the HSC how the child's assent will be determined—e.g., a signature, a verbal yes, and a nod of the head. It must be clear that the child is volunteering to participate and understands that he/she may stop or withdraw at any time. For children who are not capable of giving assent, the researcher will take care that their rights are not abridged. For example, a crying baby should be comforted before the session continues.

Waiver of Permission and Assent

Only the HSC can waive permission and assent when children are subjects of a research project, and that is only in special circumstances. Parental permission is not required in school situations when the research involves no activity by the participants that would not be required if the research were not conducted. These cases usually involve evaluation of normal instructional practices. See Section 8 below for more discussion on research in school and clinical settings.

6.3.7 Persons with Limited Capacity to Consent and Other Limitations

There are special ethical concerns about obtaining valid consent to participate in research from individuals with limited capacity such as those who are cognitively impaired as a result of mental retardation, head injury, a psychiatric condition, dementia, or other reasons. When these individuals are in schools or human service organizations, the HSC policy on Research in Schools and Human Service Organizations stated below should be consulted. Obtaining explicit consent may not be necessary for certain types of research.

The primary ethical issue with this population is whether the individuals have the capacity to understand the information presented that describes the research procedures, risks, benefits, and other aspects of the research. Obtaining consent from individuals who are cognitively impaired involves an active and, when necessary, an individualized process of presenting information in a manner that can be understood by each person. The consent process may have to be modified for individuals in the same study when they differ with respect to their capacity to understand the relevant information. It may not be possible to have a standard written form for all individuals, as is the case for most studies involving persons without limited capacity. The information presentation phase of the consent process might include tactics such as wording the information using vocabulary and grammar that are appropriate to each individual, revising the wording of the information so it is understood by each person, reading the consent form to individuals, and questioning individuals about their understanding of the information presented. The researcher has a duty to employ means such as these and others, as appropriate, to be convinced ultimately that the potential subject understands the relevant information about

the study to be conducted.

A similar consent issue pertains to individuals with other disabilities or limitations that require sensitivity when soliciting consent to participate in research. Persons with sensory disabilities or specific learning disabilities may require modifications in how information is presented to accommodate their disability and ensure valid consent. Likewise, individuals with limited formal education, those with meager English language skills, elderly persons who process information slowly, and others who, for any reason, may have difficulty understanding the requirements, risks, and benefits of the proposed research should be treated in a manner appropriate to obtain valid consent.

A second ethical concern pertains to the possibility of coercion when these individuals are receiving services from the organization or staff where the research will be conducted. Potential subjects should not be recruited by individuals who directly provide services to them. Individuals also should be told that their decision to participate or not participate in the research would not affect the services to which they are otherwise entitled.

If consent is required and the proposed subjects are children, it is always necessary that parental or guardian permission be obtained, as well as assent by the child, if the child is able to do so. In the case of adults with limited capacity, it is necessary to consider the nature of their specific cognitive impairment in light of the context of the research. Their specific impairment and the degree of risk entailed in the research should be evaluated. Capacity for consent is a contextual issue. The question is whether the individuals have the capacity to understand the information, as it will be presented for the proposed study. Some individuals may have the capacity to consent to research where the procedures are easy to understand and entail minimum risk. For these projects, individuals may be able to give valid consent if the information is presented in an appropriate manner, as discussed previously. Those same individuals may not have the capacity to understand projects that involve more complex procedures and greater risk of harm. In this case, a third party will be required to give consent. The third party should be the individual's legal guardian, if one is available. In the absence of a legal guardian, permission should be sought from the individual's parent, close relative, or an advocate. Participant assent also should be obtained when the person is able to provide it.

6.3.8 Research in Schools/Human Service Organizations (Action Research)

Research conducted in schools and human service organizations must be reviewed and approved by the HSC. The level of review and whether parental/guardian consent must be obtained has been hotly debated over the years. To help with this problem, the HSC has developed some guidelines for researchers.

Background

SIUC personnel conduct research in schools and a variety of human service organizations. Both settings define goals and allow the professionals wide latitude to implement strategies to achieve those goals, as long as the strategies fall within the constraints of relevant policies, ethics, and professional standards. Neither parental/guardian or student/client assent is required for standard activities in the settings.

The Code of Federal Regulations states that the HSC may waive written consent for research when the "research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context." [46.117(c)(2)] If the research activity is consistent in intent and method with what individuals already experience in their school or human service facility, it does not require consent or assent in those settings. Sometimes the school or service organization requires consent and assent, and SIUC researchers should comply with all relevant policies, practices, and requests from the setting where the research will be conducted.

However, many research activities conducted in schools and human service organizations are not consistent with the individuals' educational or service goals, or the research procedures do not fall within the range of acceptable practice in their setting. Those activities will require consent and assent, as applicable, and be reviewed according to the requirements of their HSC category. Examples of research that may not be consistent with educational goals are surveys or focus groups about students' personal behaviors like drug use, sexual activities, favorite television shows. Examples of research in a human service organization that may not be consistent with service goals are studies on basic biological or psychological processes, or attitudes without direct benefit to the individual participants.

Policy

Parental/guardian permission and participant consent/assent are not required in schools and human service organizations if the research activity is (a) consistent with participants' educational or service goals, **AND** (b) employs procedures that fall within the range of accepted practice for that population and setting.

The HSC will review and make the final decision on the need for parental/guardian consent.

6.3.9 Written Approval from Outside Agency, School, or Institution

When research is conducted in an agency, school, or other institution, the researcher must get signed approval on letterhead stationery from the designated authority to recruit subjects, conduct the study, or use existing data at that institution. This signed documentation must be provided to the HSC prior to the start of any research, but the HSC will not delay the reviewing process while waiting for the documentation.

The US military policies and procedures require authorized prior approval of studies involving military personnel, families and civilian personnel. Each branch of service maintains written instructions for meeting these rules. The respective regulations are as follows: Air Force IAW AFE 36-2601; Army IAW AR 600-46; Navy OPNAVINST 5300.8C.

6.3.10 Suspected Child or Elder Abuse

A researcher may encounter child or elder abuse while gathering data for a research project. If the project involves questions or situations where this information is likely to be revealed, the researcher may have to report the abuse to the proper authorities. In these cases, the researcher should include a statement in the consent form telling the subjects that if the researcher suspects that abuse has occurred, the researcher will report the suspected abuse to proper authorities.

6.3.11 Focus Groups

Participants in focus groups must be informed that research information may not be confidential, because all members of the group will be privy to whatever discussion occurs during the session. If focus groups are audio/videotaped, all members of the group must consent to be taped.

An example of a statement that could be used to explain confidentiality in focus groups is the following: "All reports based on this research and written by the researcher will maintain the confidentiality of individuals in the groups. Only group data will be reported and no participant names will be used. Since this is a group process, all members of the group will be privy to the discussions that occur during the session; therefore, the researcher cannot ensure that group members will hold this information confidential."

If the researcher wishes to describe individuals by demographic data, the researcher must ask permission to do so in the consent form. For example, a researcher may want to report that a middle-aged minority female said that neighborhood grocery store prices are too high, and so she shops at the large chain store a mile away from her home. As long as the researcher describes to the subjects the kind of identifying information that may be used, and the subjects agree to it, the researcher may use descriptive information in reports based on the focus group data.

Section 7: Common Problem Area and Solutions

7.1 Dual Relationships: Students, Trainees, Clients, and Employees as Subjects

Problems and concerns arise when the researcher's students, clients, or employees are asked to participate in research studies. The principles involved here are respect for persons and confidentiality. As described in the Belmont Report, respect for persons demands that subjects enter into the research voluntarily, without feeling any undue pressure to participate.

No explicit or implicit coercion should be used to obtain research subjects. When the researcher has a relationship with the potential subjects there is a danger that the subjects will feel obligated to participate. The HSC and the researcher must take care to ensure that subjects feel totally free to refuse to participate. Students, clients, and/or employees of the researcher may be unduly influenced by the expectation that

participation or nonparticipation will affect their academic, treatment, or employment status.

Students: Generally, it is better if faculty do not ask their own students to be subjects in their research because the students may feel compelled to participate. Students may volunteer to participate out of a belief that doing so will place them in good favor with faculty, or that failure to participate will negatively affect their relationship with the investigator or faculty generally. If faculty want to include their own students as subjects, the HSC usually requires that a third person recruit the students, gather the data, and the data should not be released to the faculty until after the end of the semester and grades have been submitted. The researcher must explain these details in the consent form so that students will not feel coerced into being subjects in their teacher's research.

Another alternative way to protect against coercion is for faculty-investigators to advertise for subjects generally, through notices posted in the school or department, rather than recruit individual students directly in the classroom.

If students will be given extra credit for research participation, the researcher must offer students alternative ways to earn extra credit. The HSC reviews these alternatives carefully to ensure that the alternative is no more onerous in time or effort than participation in the research study. (See Incentives, V. C. 2. for more discussion of this topic.)

Clients and Employees: The problems with using clients or employees are essentially the same as with students. Professionals must inform their clients that declining to participate will not affect their treatment or any services to which they are entitled. Employers must assure employees that declining to participate will not affect their job evaluations. With both groups, confidentiality of subject participation is extremely important. Consent forms must specify how the confidentiality of the data will be ensured.

7.2 Use of Internet for Surveys/Recruiting Subjects

Internet research raises a number of complex issues for the research community. A few of the problems involved are the risks versus the benefits, consent, confidentiality, and the participation of minors. Researchers' claims about the benefits of their research depend in large part on their ability to collect useful data. But conducting research on the Internet raises questions about data sampling techniques and the validity and reliability of the data collected. It is easy to mislead the researcher about geographical location, age, race, or gender. Minors may respond to a study involving inappropriate subject matter without the researcher knowing it.

Although survey research online is similar to traditional survey research, Internet research increases the subjects' risk of being identified or having their personal information accessed by people other than the researcher. The risk of exposure can surface at different stages, from data gathering, to data processing, to data storage and dissemination. Participants may not know that there is a record of the exchange in a cache somewhere on their system or saved in their Internet service provider's log files.

All SIUC researchers who are using e-mail surveys must add the following information:

- The "from" line should be the researcher's name.
- The "subject line" should be "Research Request."
- The message should state at the outset where the e-mail addresses were obtained.
- Include **either** a statement saying there will be no future mailings **or** an opt-out message that permits addressees to have their names removed from any future mailings.
- If you plan future e-mails, add the statement, "If you do not respond to this survey or return the opt-out message, you will be contacted again with this request X times during the next X weeks."
- Include the HSC e-mail address (siuhsc@siu.edu) in addition to the HSC telephone number (618-453-4533) in the last sentence of the HSC approval statement.
- Use a blind copy format so that the list of recipients will not appear in the header.

7.3 SIUC Course-Related Research Projects

Many undergraduate and graduate classes include research projects using human subjects. If the goal of the project is to provide research training and the results will not be used outside of the classroom, these projects usually do not require HSC review. The Committee assumes that the faculty member directing the projects will review each project carefully and ensure that human subjects are protected from risk. The HSC has a few guidelines to help faculty decide whether their students' research requires HSC approval.

Conditions under which HSC approval is not required for student course-related research are:

- Subjects are not identified by name or description, and
- Subjects are not selected from a vulnerable or sensitive group such as alcoholics, domestic abuse victims, prisoners, homosexuals, persons in institutional or residential settings, persons with severe disability, etc., and
- Subjects are not required to reveal anything about sensitive personal experiences or behaviors.

Any project that does not comply with all of the conditions listed above should be approved by the HSC before any subjects are recruited or data are gathered.

All classes that teach research methods should include a section on the purpose of Human Subject Committees (or Internal Review Boards) before the students begin their projects. Faculty may want to ask the students to complete the web-based training module for getting informed consent from human subjects, available on the main Human Subjects web page. This training can be completed within one hour and includes a multiple-choice test at the end.

7.4 Oral History/Film Documentaries

There has been much discussion in academia regarding oral history types of research. Oral histories and film documentaries usually involve taped interviews between the researcher and participants about a particular historical event, person or period, with intention of keeping the tapes for posterity.

In 2003 the Office of Human Research Protection (OHRP) issued a statement saying that most oral history interviewing projects are not subject to the requirements of the Department of Health and Human Services regulations because they do not involve research as defined by the HHS (ie "systematic investigation designed to contribute to generalized knowledge.") On the other hand, if these interviews involve collection and analysis of data intended to draw conclusions or generalizations, and a method or recording and/or disseminating the information then this constitutes research with humans, and the projects should be submitted to the HSC for review. The American Anthropological Association and the American Sociological Association have guidelines that address ethical issues. Both associations urge researchers to comply with federal and institutional requirements pertaining to research.

Oral history projects should:

- Include information in the consent form about how the tapes will be used in the future and who will have access to them.
- Provide participants an opportunity to have their names removed from the tapes and kept confidential in any publications.
- Provide some way to protect the privacy of any third parties who may be named in the interview.

There is a special application form for approval of oral-history/field research.

7.5 Program Evaluations

Research that involves program evaluations or quality assurance may or may not need to be reviewed by the HSC. If the purpose of the project is to develop or contribute to generalizable knowledge, it should be reviewed by the HSC. If the project is for internal purposes only, to improve or understand a program, it does not have to be reviewed by the HSC. For clarification, contact the HSC office at (618) 453-4533 to discuss the details of your project.

7.6 Use of Existing or Secondary Data

If researchers plan to use data that already exist, the HSC must review the research if the data involve humans. If the data involve documents, records, pathological specimens, or diagnostic specimens that are publicly available or if the information is recorded so that subjects cannot be identified directly or indirectly, the research will probably be reviewed

at the Category I level. If the identifiers are recorded, researchers must describe in the HSC application the procedures they will use to protect the confidentiality of the subjects. If possible, the identifiers should be removed by a person who already has access to the data before the researcher gains access to the data.

There is a special application form for research involving the use of existing or secondary data.

7.7 External Agency Deadlines and HSC Review

It is recommended that applications to the HSC be submitted for review before a proposal is sent to an external funding agency; however, the HSC realizes that agency deadlines must be met and the turn-around time is often very short. There is no need to miss an agency's deadline because you are waiting for the HSC to review your project. Researchers should submit their applications to the HSC as soon as possible after the agency deadline so that they can be reviewed as quickly as possible. If the proposal for research that involves human subjects is funded, the University will not set up an account for the project unless the HSC has approved the research.

7.8 Prisoners

Because prisoners are incarcerated, they may be under constraints that could affect their ability to make a truly voluntary decision about whether or not to participate as subjects in research. The HSC, therefore, has additional duties mandated by 45 CFR 46:302-306 to review all protocols involving prisoners as a Category III proposal, and to include on the review panel a reviewer who is either a prisoner or who has the background and experience to serve as a prisoner representative. In Illinois and in many other states, a state review panel must also approve any human subject research in state prisons. (Illinois Administration Code, Title 20 Part 106)

The HSC suggests that consent forms for research with prisoners include addresses for the researchers and the HSC, but not their telephone numbers. This may prevent unwelcome phone calls, and yet the prisoners' rights to report adverse events are still protected.

Only certain types of research involving prisoners may be approved by the HSC. They are the following:

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
3. Research on conditions particularly affecting prisoners as a class (for example, hepatitis research that is more prevalent in prisons, alcoholism, drug addiction and sexual assaults). If funded by DHHS, the Secretary of DHHS must consult with

experts and then publish the intent to approve the research in the Federal Register;
4. Research on practices that have the intent and reasonable probability of improving the health or well being of the subjects.

7.9 Research in Foreign Countries

When faculty, staff, or students conduct research with human subjects in a foreign country, there may be cultural differences that should be considered in the HSC review. Some of the differences are listed below.

1. Language: When documents must be translated into a language other than English, the researcher should provide a copy of the document in English, a copy in the language to be used, and a letter from an unbiased individual with expertise in the language (e.g., an SIUC faculty member) indicating that the translated version is complete and contains the same information as the English version.
2. Minors: When subjects are younger than 18, researchers are required to get written parental permission. However, if local regulations are such that parental permission for research in a school setting would be inappropriate, the researcher must give the HSC proof that this is inappropriate. For example, proof could be a letter saying that parental permission would be inappropriate from an authorized official in the country, or from an SIUC faculty member who is familiar with the culture.
3. Audio/video taping: When researchers audio/video tape subjects, the HSC requires a signed consent form. But in some cultures, subjects would be reluctant to sign an official form. This should be explained in the application, and the HSC will consider alternative means of documenting consent such as obtaining verbal consent on the tape. Subjects must be informed of their rights, confidentiality, and all other aspects of consent.

7.10 Non-English Speaking Subjects

When subjects do not speak or understand English well, the researcher must prepare documents in the language that subjects can understand. As described above, the researcher must provide to the HSC a copy of the document in English, a copy in the language to be used, and a letter from an unbiased individual with expertise in the language (e.g., an SIUC faculty member) indicating that the translated version is complete and contains the same information as the English version.

7.11 Recruitment Procedures and Materials

Potential subjects may be vulnerable if a study has therapeutic attributes. Any method of recruitment and use of recruitment materials must be included in the application for HSC review and approval. These materials must not be coercive or promise benefits beyond what is described in the protocol and consent. Any changes in these recruitment materials during the course of the study must also be reviewed by the HSC before put

into use. See the below University of Pennsylvania link on research recruitment materials for additional guidance.

http://upenn.edu/regulatoryaffairs/Documents/irbgui-4.pdf