

Institutional Review Board Policies



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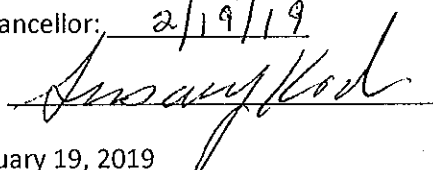
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1.0 Mission

The University of Illinois at Springfield (UIS) fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the campus. Actions taken in the review and conduct of human subjects research by UIS will be guided by the principles of respect for persons, beneficence, and justice that are set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the *Belmont Report*; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979) and with other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (U.S. Department of Health and Human Services (HHS) policies and regulations at 45 CFR 46, which are known as the Common Rule)

Any project that represents a systematic investigation designed to contribute to generalizable knowledge and that involves the collection of data through interaction or intervention with individual humans or the gathering of identifiable private information about individual humans or human biospecimens is considered human subjects research under UIS policy. This IRB policy is authorized by the UIS Human Research Protection Policy (<https://www.uis.edu/academicstaffhandbook/university-policies/>) and covers all human subjects research conducted by UIS employees (including visiting scholars) students, and contractors, as well as research conducted by individuals external to UIS when their research involves the collection of data from UIS employees or students, or the gathering of identifiable private information about UIS employees or students from records. Human subjects research is not defined in terms of particular research methods, whether qualitative or quantitative in type. Research covered by this policy includes both sponsored and unsponsored projects, data gathering for institutional research purposes, sharing of data across institutions, and student research conducted in a course or supervised tutorial context. Thus, under the UIS Human Research Protection Policy (HRP), UIS researchers must submit all such human subjects research proposals to the Human Subjects Review Officer (HSRO) or his/her designee, for review and approval **before** any data collection can begin.

Distinguishing between human subjects research and other non-research activities involving the collection of data from individual humans, such as institutional research for quality assurance or program evaluation, can be challenging. It can also be difficult to determine which research-related course assignments or educational activities require human subjects review. The IRB policy outlined in this document (and accompanying procedures) are intended to serve as a guide for the UIS community; however, faculty, staff, and students are encouraged to consult with the UIS Human Subjects Review Officer when unsure about the need for human subjects review. Human subjects research conducted by UIS staff or students, or research conducted at UIS by an individual that is not a UIS employee or student, must be supervised by a UIS faculty member, who will be designated the Responsible Research Supervisor.

Under this policy, research conducted or supported by any federal department or agency that has adopted the Common Rule constitutes a special category of research. Whenever UIS becomes engaged in human subjects research (i.e., whenever any UIS employees or students engage in any form of data collection through interaction or intervention with individual humans or the gathering of identifiable private information about individual humans from existing documentation, or any UIS employees or students are the subjects' of data collection, for the purposes of contributing to generalizable knowledge) that is conducted or supported by any federal department or agency that has adopted the Common Rule, actions taken will be in accordance with the terms of the *Federalwide Assurance* (FWA) for institutions within the U.S.A.

In order to ensure the responsible conduct of research with human subjects, UIS maintains an Institutional Review Board for the Protection of Human Subjects of Research (IRB) to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of the IRB to: (a) determine and certify that all projects reviewed by the IRB conform to the policies in this document and all applicable regulations regarding the health, welfare, safety, rights, and privileges of human subjects; and, (b) assist the investigator in complying with federal, state, and University of Illinois regulations.

1.1 Introduction

The UIS IRB Policy has been developed to provide the campus research community with an overview of the institutional policies and federal regulations governing research with human subjects and of the requirements for submitting research proposals for review by the UIS Institutional Review Board for the Protection of Human Subjects of Research (IRB). The policies outlined in this document apply to all research involving human subjects, regardless of sponsorship and performance site, if UIS faculty, staff, students, or facilities are involved.

All institutional and non-institutional performance sites for UIS, domestic or foreign, will be obligated by UIS to conform to ethical principles that are at least equivalent to those of this institution, as cited in Section 1.0 Mission (above) or as may be determined by the U.S. Department of Health and Human Services (HHS) Secretary.

1.2 Implementation

This policy shall be operative as of the date it is approved by the Vice Chancellor for Academic Affairs of the University of Illinois Springfield (VCAA), to whom the authority of Institutional Official had been delegated by the Chancellor as described in the UIS Human Research Protection Policy. In accordance with University of Illinois policy, this document shall be reviewed at least every five years and revised as necessary. Revisions may be suggested at any time by an IRB member or the staff of the Office of Research and Sponsored Programs. In order for changes to be implemented, revisions in statement of policy require approval by the UIS IRB (in compliance with IRB meeting procedures) and the Institutional Official (VCAA).

2.0 Definitions of Basic Terminology

Important basic terminology that has been used throughout this document is defined in this section. Additional definitions have been included in specific sections of the policy, as relevant.

Adverse Event: are research-related events that cause direct harm to human subjects. Any research-related physical, psychological, or social harm to subjects' occurring during the course of the research.

Affiliation Status: an individual's relationship with the University of Illinois Springfield. Non-affiliated status means that neither the individual nor an immediate family member of the individual are affiliated with the campus.

Certification: means the official notification by the institution to the supporting Federal Department or Agency, 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.

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.

Human Research Protection Program (HRPP): a systematic and comprehensive approach, taken by an organization, to ensure human subject protection in all human research conducted under the auspices of the institution.

Human Subjects Research: For the purposes of this policy *human subjects research* is defined as an activity that meets the definition of *Research* and involves *human subjects* as defined by HHS regulations.

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research (a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. If the information or biospecimens are sufficiently de-identified, the research involving them is not considered to involve a human subject (for appropriate de-identification, see OHRP's *Guidance on Coded Private Information or Specimens in Research*).

Human Subject (FDA): As defined by FDA regulations, a Human Subject is an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of a medical device, a human subject/participant also means a human on whose specimen an investigational device is used (21 CFR 50.3).

Although the term *participant* is the preferred reference in some academic disciplines, the term *subject* will be used throughout this policy because it has a long history of use across disciplines and continues to be the standard term used in applicable federal policies.

Intervention: includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subjects' environment that are performed for research purposes.

Interaction: includes communication or interpersonal contact between investigator and subject.

IRB: means an Institutional Review Board established in accord with and for the purposes expressed in this policy.

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.

Minimal Risk: the determination of the IRB 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.

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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Protocol: an application for approval of proposed research, submitted to the institution's IRB.

Primary Reviewer: an IRB member formally designated by the IRB Chair to lead a protocol review on behalf of the IRB and make a recommendation to the Chair or full IRB regarding protocol approval.

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.

Related to the research: An event is related to the research procedures if, in the opinion of the Responsible Primary Investigator or the Responsible Research Supervisor, the event is more likely than not to be caused by the research procedures and/or affects the rights and welfare of current participants.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition. Activities specifically deemed not to be research include certain journalistic and scholarly activities such as oral histories that focus on specific individuals; public health surveillance, criminal justice or criminal investigative activities,

and activities in support of intelligence, homeland security, defense, or other national security missions when authorized by the appropriate agency (condensed from 45 CFR 46.102(l)).

Research: as defined by the Food and Drug Administration (FDA) regulations under Title 21, Part 56, Institutional Review Boards, is any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under Section 505(i) or 520(g) of the Act, or is not subject to requirements for prior submission to the Food and Drug Administration under these Sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding non-clinical laboratory studies. An experiment, as defined in 21 CFR 312, includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice.

Responsible Principal Investigator (RPI; also known as Lead Investigator): the individual who has lead responsibility for conducting the research. The RPI may be a UIS employee, student, or external individual. Whenever the Responsible Primary Investigator is not a UIS full-time faculty member, the research must be supervised by a non-visiting UIS faculty member, who will be designated as the Responsible Research Supervisor (RRS).

Responsible Research Supervisor (RRS): a non-visiting member of the UIS faculty (i.e., full-time tenured/tenure track or non-tenure track faculty) who has supervisory responsibility for the protection of the subjects' and the conduct of the human subjects research described in the research protocol submitted for review under the UIS Policy and Procedures for Human Research Protection. UIS students and graduate assistants may serve as RPI but cannot serve as RRS.

Systematic Investigation: For the purposes of this policy, a *systematic investigation* is an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question. Activities *designed to develop or contribute to generalizable knowledge* are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

UIS Employee: a UIS faculty or staff member, adjunct, visiting scholars, graduate assistants and student workers. UIS students are not considered UIS employees, unless there is a specific appointment pursuant to established University process.

Unanticipated Problem Involving Risks to Participants or Others (Unanticipated Problem): Any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others, or that participants or others are at increased risk of harm.

Unexpected: An event is unexpected when its specificity and severity are not accurately reflected in the informed consent document.

Vulnerable Populations: is a subgroup of the population who because of their status are at greater risk to be coerced or influenced to participate in human subjects research. This subgroup includes individuals with acquired immune deficiency syndrome (AIDS), fetuses, minorities, children (minors), prisoners, decisionally impaired persons, elderly and aged persons, international research subjects', terminally ill patients, traumatized and comatose patients, students, and employees.. Researcher should consider the fact that vulnerability can also be context-specific. It is important for researchers to consider the context as well as what is being asked of whom, and under what conditions. The same factors that make subjects available for research make them vulnerable to overuse.

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

3.0 Institutional Authority

The Chancellor of UIS has designated the Vice Chancellor for Academic Affairs (VCAA), as the *Institutional Official* (IO) responsible for carrying out the UIS Human Research Protection program. The IO is responsible for ensuring that the UIS IRB has the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subjects research. The IO is the point of contact for correspondence addressing human research with the HHS Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). In the performance of these duties, the IO has the authority to delegate such activities as may be necessary in order to fulfill these duties.

The IO has designated the Associate Vice Chancellor for Research and Institutional Effectiveness (AVCRIE) as the *Human Subjects Review Officer* (HSRO) for the UIS campus. The AVCRIE has the authority to designate a member of the faculty to act as the HSRO, following the appropriate procedures. The HSRO has expert knowledge in regulatory issues regarding human subjects, and serves as Chair of the *Institutional Review Board for the Protection of Human Subjects of Research* (IRB).

The UIS IRB has jurisdiction over all human subject research (as defined above) conducted under the auspices of the institution. Research under the auspices of the institution includes research conducted at this institution, conducted by or under the direction of any employee or agent of this institution (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or involving the use of this institution's non-public information to identify or contact human subjects.

3.1 Principles Governing IRB Review of Research

It is the duty of the UIS IRB to review and make decisions on all protocols for research involving human subjects. The IRB is guided in its decision-making by ethical principles, and federal, state, and University regulations regarding research with human subjects. The primary responsibility of the IRB is the protection of research subjects from undue risk and from deprivation of personal rights and dignity. This protection is best assured by consideration of three principles, which are the touchstones of ethical research:

- (1) voluntary participation by the subjects', indicated by free and informed consent, must be assured;
- (2) an appropriate balance must exist between the potential benefits of the research to the subject or to society and the risks assumed by the subject; and
- (3) the selection of research subjects must be the result of fair procedures and outcomes.

These principles are summarized as **respect for persons, beneficence, and justice**, each of which is discussed below. Researchers should be especially cognizant of the need to provide a substantive and cogent rationale for proposed research with subject groups drawn from vulnerable populations. For example, federal guidelines explicitly recognize vulnerable populations in a broader context. Subject vulnerability is always a relevant consideration for researchers, and it is the responsibility of researchers and IRB members to consider the context of specific research purposes and methods (i.e., to consider what information and actions are required of whom, under what conditions, and for what purposes).

3.1.1 Respect for Persons: Voluntary Participation and Informed Consent

One of the most important elements in any research involving human research subjects is the assurance of voluntary informed consent. Any person who is to be a research subject, whether the research is designed for his/her own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what they will be asked to do as a research participant and what the potential risks and benefits of their participation are. The person must give his/her consent freely, without pressure or inappropriate inducement. The IRB at UIS strives to ensure voluntary informed consent of research subjects through careful review of the recruitment and consent process, and of the consent form or information sheet to be used with subjects'.

The informed consent concept is extended to those studies in which the subjects' are not able to give personal consent for themselves. Here the consent document is addressed to those who have been designated responsible for the research

subjects' well-being (e.g., parents or legal guardians of children). The IRB's concern is to verify that the consent process and document are likely to assist these persons to make an informed decision, which is in the best interest of the research subject. The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential subjects'. The IRB must exercise special care when considering subjects' whose ability to give free and informed consent may be compromised in any way.

3.1.2 Beneficence: The Risk-Benefit Ratio

The IRB is charged with deciding, for any proposed activity that falls under its jurisdiction, whether: "The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept [those] risks" (Federal Register, May 30, 1974).

The assessment of the risk/benefit relation is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological, and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. In reviewing applications, the IRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and document. While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess the risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any research subject at risk, however minimal. Thus, the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB.

3.1.3 Justice: The Fair Election of Research Subjects

Both the risks and the potential benefits of research should be spread fairly among potential individual research subjects and research subject groups. Study design and selection of subjects' should avoid bias for or against particular social, racial, sexual, or ethnic groups.

Sharing Research Risks. The guiding principle in the ethical selection of research subject groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a protocol that carries elevated levels of risk might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (e.g. institutionalized people or prisoners; patients at free clinics primarily patronized by people unable to afford other medical care) simply because they are easily accessible or can be persuaded to participate. An undue share of research risks should not also burden groups already burdened by other factors. Rather, attempts should be made to include a fair sampling of the populations who might benefit from the study. When research involves persons whose autonomy is compromised, it is expected that the research bear some direct relationship to the conditions or circumstances of the research subject population. In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations. For example, investigational drugs are usually tested in adults before they are tested in children, and investigational drugs and procedures may be tested in healthy volunteers before being tested in patients.

Sharing Research Benefits. In recent years, increasing attention has been paid to the rights of various groups to be included in research. As individuals and through advocacy groups, many patients have come to insist on having access to experimental treatments as these experimental treatments may potentially provide the best medical care available. In addition, researchers, ethicists, and public officials have recognized that because many clinical trials focus primarily on white middle-class research subject groups, the results of some trials were of questionable value for members of other social, racial, and ethnic groups. As a result, both the National Institutes of Health and the Food and Drug Administration now require that study design include as broad a range of research subjects as feasible and that data are analyzed to uncover responses that differ between groups. For example, although women of child-bearing potential and pregnant and nursing women previously were routinely excluded from new drug trials, it is now required that whenever possible these women be asked to make their own choices after being fully informed of the risks of the research.

3.2 Assurance of Compliance

UIS holds Federalwide Assurance (FWA 00001213). The FWA is an assurance of compliance with the federal regulations for the protection of human subjects in research that is federally funded. The FWA is also approved by

OHRP for federal-wide use, which means that other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research that they conduct or support.

In its FWA, UIS has opted to apply the Common Rule to human subjects research that is federally funded. This includes pass-through funding for which the original source of support is a federal agency. The subparts of 45 CFR 46 only applies to research funded by HHS. See Section **11.0 Vulnerable Populations** for a more detailed discussion of the application of the subparts. However, regardless of funding source, the UIS IRB routinely relies on the principles and guidelines of the Common Rule in making determinations regarding the protection of human subjects of research and the level of review required for approval of research protocols.

3.3 Classified Research:

If research involves information, analyses, or results of research that are classified by the sponsor or a third party (i.e., research for the federal government under an agreement which is classified as secret or confidential), it is considered *classified research*. UIS will not accept or perform research that the IRB determines is classified.

3.4 Legal Compliance

The UIS IRB relies on the Office of General Counsel of the University and on the Campus Legal Counsel for the interpretation and application of federal and state laws and regulations, and the laws of any other jurisdiction where research is conducted as they apply to human subjects research.

4.0 UIS Institutional Review Board

The UIS IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of this institution. There is one campus-wide IRB.

The UIS IRB reports directly to the Vice Chancellor for Academic Affairs (and who serves as the Institutional Official) and is chaired by the HSRO.

4.1 Authority of the IRB

The IRB ensures that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB reviews all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The application or protocol, the consent/assent document(s), tests, surveys, questionnaires and similar measures, and recruiting documents are examples of documents that the IRB reviews.

Before any human subject is involved in research in relationship to this institution, the IRB will give proper consideration to (a) the risks to the subjects'; (b) the anticipated benefits to the subjects' and others; (c) the importance of the knowledge that may reasonably be expected to result; and (d) the informed consent process to be employed.

The IRB has the authority to suspend, place restrictions on, or terminate approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with serious harm to subjects. By its recommendations to the VCAA, the IRB can effect action that withholds or withdraws financial or approved support from projects involving human subjects that are not in compliance with University policies or federal regulations. Further action may be taken by the VCAA or other authorities for non-compliance, according to their policies and procedures. The IRB has the authority to observe or have a third party observe the consent process and the research if the IRB determines such steps are indicated for the protection of human subjects of the research. UIS administrators (departmental chairs, deans, directors, division heads) should remind prospective investigators of IRB requirements whenever a proposed activity involves human subjects.

4.2 Jurisdiction of the IRB

The IRB jurisdiction extends to all research (funded and not funded) involving human subjects conducted at UIS, as well as research conducted elsewhere by UIS faculty, staff, and students, including exempt research activities for which limited IRB review is a condition of exemption (see Section 8.3.3 **Categories of Research Permissible for Exemption**).

4.3 IRB Relationships to Other Entities

The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, independently determines whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects, which includes but is not limited to research conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects regulations.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may **not** approve research if it has been disapproved by the IRB.

4.3.1 Relationships with Other Institutions

UIS may choose, on a case-by-case basis, to provide human research protection oversight for another institution. In order for UIS to provide this oversight, a formal relationship must be established between the campus and the other institution through an Authorization Agreement. This relationship must be formalized, following the appropriate procedures, before the campus will accept any human research proposals from the other institution.

In the conduct of cooperative research projects, UIS acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. When a cooperative agreement exists, UIS may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. UIS will enter into a single IRB arrangement when it is a condition of federal funding (e. g. NIH policy on multi-site research).

4.4 Roles and Responsibilities

4.4.1 Chairperson of the IRB

The task of making the IRB a respected part of the institutional community is shared equally by all members of the IRB; however, the IRB Chair has special responsibility for ensuring that the IRB processes and decision-making follow the principles and established guidelines for the responsible conduct of research, as described in Section 1.0 of this document, and that IRB decision-making is fair, impartial, and immune to any perceived pressure from sources of competing interest. The IRB Chair should be a highly respected individual, from within the campus, capable of managing the IRB, and the matters brought before it with fairness and impartiality.

At UIS, the HSRO serves as the Chair of the IRB. The IRB Chair advises the IO about IRB member performance and competence. The Chair of the IRB is a voting member with indefinite term of service.

4.4.2 Vice-Chair of the IRB

In consultation with the IRB members, the Chair of the IRB may appoint a Vice Chair to serve for a renewable three-year term. Any change in appointment, including reappointment or removal, requires written notification. The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority, and duties as Chair.

4.4.3 Subcommittees of the IRB

The IRB Chair may designate one or more other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions described below. IRB members assigned to lead protocol reviews or serve on review subcommittees will be matched as closely as possible with the disciplinary field of the research under review. At least one member of a review subcommittee must have served on the IRB for a minimum of two years.

Duties of IRB members assigned to lead protocol reviews or serve on review subcommittees may include the following:

Serve as designees by the IRB Chair for the **exempt or expedited review** of new or continuing protocols, and/or modifications of continuing protocols.

Review and approve the revisions requiring only simple concurrence submitted by investigators for a protocol given provisional approval, i.e. "Approval Pending Revisions", by the full IRB committee.

Conduct an inquiry. A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to conduct an inquiry into allegations of non-compliance. The subcommittee is given a charge by the IRB, which can include any or all of the following:

- Review of protocol(s) in question.
- Review of any relevant documentation, including consent documents, case report forms, subjects' investigational files, etc., as they relate to the investigator's execution of her/his study involving human subjects. Interview of appropriate personnel if necessary.
- Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting.
- Recommend actions as appropriate.

Conduct an on-site review. Determination of the review interval and the need for additional supervision and/or participation are made by the IRB on a protocol-by-protocol basis. For example, for an investigator who is performing research having elevated levels of risk, or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by an IRB subcommittee might occur, or approval might be subject to an audit of study performance after a few months of enrollment or after enrollment of the first several subjects'.

4.5 Resources for the IRB

The VCAA provides reasonable resources to the IRB, including adequate meeting and office space, and staff for conducting IRB business. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and staff. The resources provided for the IRB will be reviewed during the annual budget review process.

4.6 Conduct of Quality Assurance

To allow for quality assurance determinations, researchers will maintain research files for no fewer than three years after completion or termination of the research. It is understood that Researchers may be subject to professional, legal, or other regulatory requirement to maintain research records for longer periods of time. As provided in University policy, investigations and audits of ongoing research or records will be conducted when the IRB directs an audit be conducted or a complaint or allegation of non-compliance is received. In addition, the staff will conduct "for cause" and "not for cause" audits of research.

Periodic reviews of the human research protection program at the University of Illinois Springfield are also conducted by the University's internal auditors. University reviews may include but are not limited to any of the following elements as described in written documents and as implemented in practice:

- Institutional and IRB policies and procedures for protecting human subjects
- Organizational issues affecting systemic protections for human subjects
- IRB documentation and records-keeping practices
- Adequacy of IRB forms and templates

- Standards and practices for initial and continuing IRB review
- Standards and practices for obtaining and documenting informed consent
- Standards and practices for monitoring compliance with IRB determinations
- Standards and practices for monitoring unanticipated problems and adverse events
- Methods and effectiveness of communication between the IRBs and research investigators
- Training of IRB members, investigators, research personnel, and administrative staff

All recommendations for improvement in the human research protections program will be considered by the VCAA and the HSRO. Changes in the program will be presented to the IRB for review prior to implementation. Changes to this policy must follow Section 1.2.

5.0 IRB Membership

IRB members are selected from the faculty and from the community-at-large to ensure representation of professional expertise and community attitudes.

5.1 Composition of the IRB

The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

The IRB will be sufficiently qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The IRB shall not consist entirely of members of one profession.

Reasonable efforts will be made to ensure that IRB membership represents diversity in race/ethnicity, gender, and academic discipline, and exercises sensitivity to community attitudes.

The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

One member may satisfy more than one membership category.

If the IRB regularly reviews research that involves a vulnerable category of subjects' (e.g., children, prisoners, or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these subjects'. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants, either as members of the IRB or as consultants (see Section 5.3 Use of Consultants).

The Chair of the IRB is a voting member.

An accompanying procedure describes the appointment of regular and alternate members to the IRB.

5.2 Alternate members

The IRB has the option of appointing alternate members. The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the

primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting.

An accompanying procedure describes the assigning, and use of, alternate members.

5.3 Use of Consultants (Outside Reviewers)

When necessary, the HSRO may solicit individuals from the University or the community with competence in special areas to assist in the review of issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB. For example, federal policy requires that a prisoner representative must be present for the review of any protocols involving prisoners as human subjects of research.

5.4 Duties of IRB Members

The agenda, protocols, submission materials, proposed informed consent forms, and other appropriate documents are distributed to members prior to the convened meetings at which the research is scheduled to be discussed. Members review the materials before each meeting, in order to participate fully in the review of each proposed research project. Research proposals, protocols, and supporting data will be treated as confidential information, and should be disposed of appropriately.

5.5 Attendance Requirements

Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the HSRO or the Grants & Contracts Coordinator, or equivalent IRB staff member (GACC). The procedures described in the Alternates SOP should be followed.

If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate (See Section 5.2 Alternate members), the alternate can serve during the primary member's absence, provided the IRB has been notified in advance.

5.6 Training / Ongoing Education of HSRO and IRB Members in Regulations and Procedures

A vital component of a comprehensive human research protection program is an education program for the HSRO and the IRB members. UIS is committed to providing training and an ongoing educational process, related to ethical concerns and regulatory and institutional requirements for the protection of human subjects, for the HSRO and IRB members. Appropriate procedures will be followed for ensuring adequate education and training of IRB personnel.

5.7 Liability Coverage for IRB Members

The University's insurance coverage applies to employees and any other person authorized to act on behalf of the University for acts or omissions within the scope of their employment or authorized activity.

5.8 Review of IRB Member Performance

The IRB Members' performance will be reviewed on an annual basis by the IO, in consultation with the HSRO, according to procedures established by the HSRO. Members who are not acting in accordance with the IRB's mission or policies and procedures or who have an undue number of absences may have their appointments terminated.

6.0 IRB Records

6.1 Staff to the IRB

The Director of Research Administration, a member of the staff of the VCAA, serves as staff to the IRB, or may designate a staff member (Grants & Contracts Coordinator or equivalent) to have the day-to-day responsibilities for managing and maintaining the files of the IRB. This includes responding to faculty, student, and staff questions about human subjects research, consulting with the HSRO as needed, working with investigators to improve and clarify

protocols and related documentation, and organizing and documenting the review process. The GACC also works closely with the HSRO in the development of policy and procedures. The GACC prepares IRB meeting packets, records IRB meeting minutes, maintains IRB databases and correspondence, and assists the HSRO.

6.2 Required Documentation

The GACC must prepare and maintain adequate documentation of the IRB's business and actions, including copies all items reviewed. Documentation includes but is not limited to:

- subject recruitment materials;
- scientific evaluations (if any) that accompany the proposals;
- approved consent documents (including HHS-approved sample consent documents when necessary);
- any proposed amendments to the protocol and the IRB action taken on each amendment;
- reports of injuries to subjects' and serious and unexpected adverse events;
- documentation of protocol violations; and
- documentation of non-compliance with applicable regulations.

Any new research findings that may be relevant to subjects' willingness to continue participation in the research will be provided to subjects', must be maintained with the related research proposal, and, when reviewed at an IRB meeting, must be documented in the minutes. Progress reports, continuing review documents, and correspondence between the IRB and the investigator must also be retained.

IRB records must also document any determinations required by the regulations and protocol-specific findings supporting those determinations, such as Letters of Waiver of Jurisdiction, Documentation of Verified Exemptions, initial and Continuing Review of Expedited Review, and Limited Review of protocols. Appropriate procedures for conducting and documenting these determinations will be developed by the HSRO.

6.3 Minutes of IRB Meetings

Proceedings must be written and available for review by the next regularly scheduled IRB meeting date. Once approved by the members at a subsequent IRB meeting, the minutes must not be altered by anyone, including a higher authority.

Minutes of IRB meetings must contain sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

Procedures for recording, reviewing, correcting, approving, and distributing minutes of the full IRB meetings will be established by the HSRO.

6.4 Membership Rosters

A membership list of IRB members must be maintained within the Office of Research and Sponsored Programs; it must identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list must contain the following information:

- Name
- Earned degrees

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- Affiliated or non-affiliated status (*non-affiliated* means neither the member nor an immediate family member of the member may be affiliated with the campus)
- Status as scientist (physician-scientist, other scientist, non-scientist, or social behavioral scientist). For purposes of this roster, IRB members with research experience are designated as scientists. Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) and previous or current conduct of research. Students being trained in research fields will be designated as scientists.
- Indications of experience, such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations.
- Representative capacities of each IRB member, including which IRB member is a prisoner representative (as required by Subpart C) and which IRB members are knowledgeable about or experienced in working with children, cognitively impaired individuals, and other vulnerable populations locally involved in research.
- Role on the IRB (Chair, Vice Chair, member, staff to the IRB)
- Voting status (Any *ex officio* members are non-voting members)
- Alternate status, including the member they alternate with
- Relationship (e.g., employment) between the individual IRB member and the organization

The GACC will keep the IRB membership list current.

6.5 Records Retention Requirements

All records must be accessible for inspection and copying by authorized representatives of the OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

The above detailed IRB records must be stored securely in the VCAA's Office and must be retained for at least three years, in accordance with records maintenance policies of the state of Illinois. Records are maintained in locked file cabinets and/or locked offices within the VCAA's Office and are available only to authorized staff and IRB members. If a protocol is cancelled without subject enrollment, IRB records will be maintained for at least three years after cancellation.

Documentation of consent must be stored securely by the Lead Investigator and retained for at least three years after completion of the research.

Records maintenance and destruction will follow the procedures of the UI Records and Information Management Services.

6.6 Written Procedures and Guidelines

The UIS IRB Standard Operating Procedures (SOP) detail the procedures and regulations governing research with human subjects, the requirements for submitting research proposals for review by the UIS IRB, and the operations of the IRB office.

The HSRO will keep the UIS research community apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues. The IRB policies and procedures will be available on the UIS Research and Sponsored Programs website.

7.0 Investigator Responsibilities

Responsible Principal Investigators are ultimately responsible for the conduct of research and have primary responsibility for protecting the rights and welfare of human subjects. Principal Investigators are responsible for

complying with all applicable provisions of the University of Illinois Springfield's FWA, federal and state laws and regulations, and the University's policies and procedures. Principal Investigators may delegate research responsibility; however, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

In order to satisfy the requirements of this policy, investigators who conduct research involving human subjects must:

- develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
 - develop a research plan that is scientifically sound and minimizes risk to the subjects';
 - have sufficient resources necessary to protect human subjects, including:
 - access to a population that would allow recruitment of the required number of subjects'
 - sufficient time to conduct and complete the research
 - adequate numbers of qualified staff
 - adequate facilities
 - a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions
 - medical or psychological resources available that subjects' might require as a consequence of the research;
 - protect the rights and welfare of prospective subjects';
 - have plans to monitor the data collected for the safety of research subjects;
 - have a procedure to receive complaints or requests for additional information from subjects' and respond appropriately;
 - ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff;
 - obtain and document informed consent as required by the IRB and ensure that no human subject is involved in the research prior to obtaining consent;
 - ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research;
 - comply with all IRB decisions, conditions, and requirements;
 - ensure that protocols receive timely continuing IRB review and approval;
 - report unexpected or serious adverse events problems that require prompt reporting to the IRB (see Section 8.9 **Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events** below);
 - obtain IRB review and approval in writing before changes are made to approved protocols or consent forms;
- and**
- seek IRB assistance when in doubt about whether proposed research requires IRB review.

7.1 Investigators

Responsible Principal Investigators

At UIS, only full-time faculty members or University employees with full-time research appointments may serve as the Responsible Principal Investigator (RPI) on a research project involving human subjects. The IRB may waive this requirement following appropriate procedures.

Staff, adjunct faculty of the University of Illinois Springfield, and other investigators whose status is considered to be “in training” (i.e. post-doctoral researchers) may only serve as a Responsible Principal Investigator if they have a full-time faculty member as the Responsible Research Supervisor. Otherwise they may serve as a co-investigator.

The **Responsible Research Supervisor (RRS)** must be a faculty member with full-time appointment at the University. An RRS is required to sponsor the human subjects research project of a non-faculty RPI.

The IRB recognizes one Responsible Principal Investigator (RPI) for each study. The RPI has ultimate responsibility for the research activities. The RRS has supervisory responsibility for the protection of the subjects and the conduct of the human subjects research described in the research protocol.

Protocols that require skills beyond those held by the Responsible Principal Investigator must be modified to meet the investigator’s skills or have one or more additional qualified faculty as Co-Investigator(s).

Student Investigators

Students may serve as Responsible Principal Investigators only if they have a faculty sponsor who will serve as the Responsible Research Supervisor for the research.

Research Team

The research team includes the RPI and other individuals, also known as key personnel, who contribute to the scientific development or execution of a project in a substantive, measurable way, whether they receive salaries or compensation under the protocol or not.

7.2 Protocol Development and Submission

When developing a protocol, the Responsible Principal Investigator or a member of the protocol research team must follow the procedures described and forms posted on the website of the Office of Research and Sponsored Programs.

7.3 Changes to Approved Research

Investigators must seek IRB approval before making any changes in approved research--even when the changes are planned for the period for which IRB approval has already been given--unless the change is necessary to eliminate an immediate hazard to subjects’ (in which case the HSRO must then be notified at once).

NOTE: IRB-approved amendments to ongoing research do **not** extend the original approval expiration date.

7.4 Continuing Review after Protocol Approval

Ongoing research studies (unless exempted from review or reviewed under minimal-risk expedited procedures) must be reviewed by the IRB at least annually, or more often if the IRB finds that the degree of risk to subjects’ warrants more frequent review. This renewal must occur before the expiration date noted on the approved protocol; otherwise, subject recruitment/enrollment must be suspended and, if the research is HHS-sponsored, the Agency must be notified. However, if the IRB determines that there is an overriding safety concern and/or ethical issue or that it is in the best interests of the individual subjects to continue participating in the research activities, the IRB may permit the subjects to continue in the study for the time required to complete the CR process.

7.5 Required Reports to the IRB

7.5.1 Unanticipated Problems

Responsible Principal Investigators must report to the IRB as soon as possible, but in all cases within 5 working days of any:

- adverse events which in the opinion of the Principal Investigator are both unexpected and related;
- an unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk;
- information that indicates a change to the risks or potential benefits of the research. Examples include:
 - an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
 - a paper published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
- a breach of confidentiality.
- incarceration of a participant in a protocol not approved to enroll prisoners;
- change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant;
- complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team;
- a protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm;
- an event that requires prompt reporting to the sponsor; or
- a sponsor-imposed suspension for risk.

7.5.2 Complaints, Non-compliance and Protocol Deviations

Investigators must report all complaints and concerns from subjects', non-compliance by research staff, and any protocol deviations to the IRB, following the appropriate procedures. (see Section 8.9 Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events).

7.5.3 Progress Reports

Investigators must report the **progress of the research** to the IRB in the manner and frequency prescribed by the IRB, but no less than once a year. A request for Continuation Review will count towards the required annual report.

Once data collection has been completed and the research is closed at either the University of Illinois Springfield or other sites, the Principal Investigator must submit a closure report and then is no longer required to submit any further reports of the research to the IRB.

7.6 Investigator-Required Record Keeping

Investigators must retain copies of approved IRB documents, and implement a system to comply with approval expiration dates.

In addition to providing a copy of the signed and dated consent form to each subject, a copy must be stored securely by the Responsible Principal Investigator (RPI) and placed in the subjects' file or medical record (if the subject is a patient and this requirement has not been waived by the IRB), and a copy must be retained by the RPI for a **minimum of 3 years after completion of the research.**

7.7 Conflict of Interest – Investigators

All Investigators and key research personnel must follow the University of Illinois Conflict of Commitment and Interest Policy. Key research personnel are those individuals who (a) recruit human subjects; (b) obtain consent from human subjects; (c) collect data from human subjects; or (d) evaluate the response of human subjects. Where a conflict of interest exists, with a protocol involving human subjects, the RPI must develop and submit a conflict management plan for the IRB to consider along with the proposed protocol. The HSRO/IRB Chair (or designee) will review the conflict management plan to determine if the conflict will adversely affect the protection of human subjects and if the management plan is adequate.

A copy of the final, approved conflict management plan will be filed in the Office of the VCAA.

The IRB application asks protocol-specific questions regarding conflict of interest for the investigators and key personnel. As part of its review process, the IRB will make a determination as to whether the conflict adversely affects the protection of human subjects. If a conflict of interest exists, final IRB approval cannot be given until an approved conflict management plan that adequately protects the human subjects in the protocol is in place.

If the conflict of interest status of an investigator changes during the course of a study, the individual is required to notify the IRB Office within ten working days of the change. The IRB will review the change as a modification to the protocol.

At the time of continuing review, the investigator will be asked whether there has been any change in the conflict of interest status relating to the research. The IRB will review conflict of interest as part of its continuing review.

7.8 Training and Ongoing Education of Principal Investigator and Research Team

UIS is committed to providing training and an ongoing educational process for investigators and members of their research teams related to ethical concerns and regulatory and institutional requirements for the protection of human subjects. Mandatory education and certification must be completed before IRB approval of any new project, revisions or amendments to existing projects, or renewals of existing projects can be granted. Individuals in the following categories are required to complete an approved Human Subjects Protections Education Program, and must provide evidence of current certification (i.e., completed within the last three years):

- all UIS IRB members;
- UIS faculty and staff serving as Responsible Principal Investigators or Responsible Research Supervisors;
- UIS faculty, staff, and students conducting informed consent procedures for research;
- UIS faculty and staff supervising students conducting research with human subjects; and
- Principal Investigators from non-UIS institutions who are conducting research at UIS with the approval of the UIS IRB and who do not have certification of education from another IRB carrying FWA.

Information about the protection of human subjects of research will be made available on the UIS IRB website on an ongoing basis to ensure that the campus research community is apprised of current regulatory and policy requirements and training opportunities.

7.9 Subject Recruitment

Investigators are responsible for recruiting research subjects in a manner that is fair, ethical, and equitable. IRB approval is required for all recruitments, procedures, and materials. Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive. Recruitment materials should adequately describe any remuneration associated with services as a research subject, but shall not be displayed in such a manner as to emphasize payment as the primary incentive for involvement in the research.

7.10 UIS Students and Employees as Subjects

When UIS students and/or employees are being recruited as potential subjects', researchers must ensure that there are additional safeguards for these research participants. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to subjects' that neither their academic status nor grades, or their employment, will be affected by their participation decision. Additionally, researchers must follow the Campus-Wide Survey Policy and submit survey requests to the UIS Institutional Data Steering Committee.

To minimize coercion, investigators should avoid, whenever possible, the use of their students and employees in procedures which are neither therapeutic nor diagnostic. In these latter situations, investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes **other than their own**. When entering a classroom to recruit students and conduct research (e.g., administer a survey), investigators must do so at the end of the class period to allow non-participating students the option of leaving the classroom, thereby alleviating pressure to participate.

7.11 Departmental Subject Pools

Departments may create a subject pool consisting of students enrolled in their courses for which course-related extra credit may be earned or courses in which research-related exercises are required. Students who are enrolled in courses requiring participation in research-related exercises are notified at the time of enrollment that as part of the course requirements they will be encouraged to serve as research subjects in the subject pool for a designated number of hours. Students who do not wish to participate as subjects' in research projects must be provided with alternate equivalent task or assignment options.

Departments are expected to conduct all research and training in accordance with the ethical guidelines set forth by the Responsible Conduct of Research program described on the UIS Research and Sponsored Programs website.

Departments who wish to create subject pools must annually register with the IRB.

7.12 Remuneration to Subjects

Remuneration to research subjects may be an incentive for participation or a way to reimburse a subject for travel and other expenses incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, investigators must take care to avoid coercion of subjects. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study.

The IRB must review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence.

Credit for payment should accrue and not be contingent upon the participant completing the entire study. Any amount paid as bonus for completion of the entire study should not be so great that it becomes coercive.

The IRB does not allow the entire payment to be contingent upon completion of the entire study. Payment in exchange for referrals of prospective participants (i.e., finder's fees) is not permitted. Similarly, payment designed to accelerate recruitment (i.e., bonus payments tied to the rate or timing of enrollment) is also not permitted.

The consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed). In the event that prizes or gift cards are given out on a lottery basis, the consent form must clearly state the probability of receiving the prize, calculated as a ratio derived from the number of prizes compared to the expected number of research participants.

In some circumstances, the University of Illinois Office of Business and Financial Services (OBFS) will require identifying information to issue checks, cash, or gift certificates to subjects' (see Section 8.4 *Payments to Human Subjects* on the OBFS website)). Generally speaking, payments to any individual more than \$200 will require the following identifying information: name, address, and Social Security Number. For such studies, the consent form must clearly state that subjects' will be required to provide this information in order to receive payment.

7.13 Investigator Concerns

Investigators who have concerns or suggestions regarding the UIS human subjects of research protection program should convey them to the IO or other responsible parties (e.g., Human Subjects Review Officer, college Dean, departmental Chair), as appropriate. The Institutional Official will research issues of concern, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the GACC will be available to address investigators' questions, concerns and suggestions.

7.14 Student Research

Given that student-researchers conduct research as part of degree- or course-requirements, *a faculty member ultimately shares responsibility for the protection of the subjects*, even if the student is the primary researcher and actually directs the project. However, student-researchers are responsible for adhering to IRB policy and following research protocol as approved by the IRB. Student-researchers should immediately report any protocol deviations, or problems with the research process, to their Responsible Research Supervisor. Accordingly, undergraduate and graduate students must have a faculty sponsor who will serve as the Responsible Research Supervisor on the study. The faculty research supervisor assumes the responsibility for students engaged in independent research under their supervision, and instructors are responsible for research that is conducted as part of a course.

7.14.1 Course Projects Involving Research with Human Subjects

Learning how to conduct ethical human subjects' research is an important part of a student's educational experience. The IRB is ultimately responsible for determining whether or not a research activity falls under its jurisdiction. Below are guidelines for instructors to help design research activities that are part of a course requirement for the purposes of learning experience only and that are not designed to develop or contribute to generalizable knowledge, may not require IRB review and approval if all of the following conditions are true:

- results of the research are viewed only by the course instructor for teaching purposes and are discussed within the classroom for teaching and learning purposes;
- results of the research are not made public through presentation (outside of the classroom) and are not published in paper or electronic format (e.g., cannot be made available on the internet, cannot be published in a journal, etc.);
- research procedures involve no more than minimal risk;
- vulnerable populations (e.g., children under age 18, prisoners, persons who are cognitively impaired, etc.) are not targeted for participation as research subjects;
- data collected are recorded in such a manner that the subjects are not identifiable*; and
- when appropriate, an informed consent process is in place.

[*NOTE: images in videotapes, photographs, and voices on audiotape are identifiable, so such procedures require IRB review.]

Responsibility of the Course Instructor

The course instructor serves as the Responsible Research Supervisor (RRS) and is responsible for communicating to the IRB the human subjects research-related projects in their classroom, and to their students the ethics of human subjects research, for ensuring the protection of human subjects (including ensuring that a process is in place for obtaining voluntary informed consent from research subjects' when appropriate), and for monitoring the students' progress.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should:

- understand the elements of informed consent;

- develop appropriate consent documents;
- plan appropriate strategies for recruiting subjects’;
- identify and minimize potential risks to subjects’;
- assess the risk-benefit ratio for the project;
- establish and maintain strict guidelines for protecting confidentiality; and
- allow sufficient time for IRB review and completion of the project.

In making a determination of whether or not a class research project requires IRB review, the instructor is required to contact the [HSRO](#) or designee for a judgement on IRB jurisdiction.

UIS policy and procedures, educational modules, forms, and related information can be found on the UIS IRB website.

7.14.2 Individual Research Projects Conducted by Students

Independent study projects, senior theses, undergraduate research projects, masters and advanced degree research, and similar exercises that involve the collection of data from human subjects as part of a systematic investigation designed to develop or contribute to generalizable knowledge are considered research activities meeting the federal definition of human subjects research and must be independently submitted by the student-researcher for IRB review. It is important to keep in mind that any human subjects research activity that will ultimately contribute to part or all of a thesis, dissertation, or other type of publication or presentation must go through the IRB review process prior to enrolling subjects’ and collecting data. IRB review cannot occur after a study has begun.

Students and advisers should contact the [GACC](#) with any questions.

8.0 IRB Review

These guidelines apply to all research involving human subjects, regardless of sponsorship and performance site, conducted under the auspices of UIS.

8.1 Human Subjects Research Determination

Responsibility for the initial determination as to whether an activity constitutes human subjects research rests with the RPI. The RPI should make this determination based on the definitions of *human subject* and *research* in Section 2. UIS will hold the RPI responsible if the determination is not correct, so investigators are urged to request a confirmation that an activity does not constitute human subjects research from the Office of Research and Sponsored Programs. The request may be made verbally, by phone contact, by email, or through a formal written communication, such as the use of a Decision Request Form. All requests must include sufficient documentation of the activity to support the determination.

The HSRO or designated staff will make the determinations according to whether the activity meets the definition of *research* and involves *human subjects* using the IRB Reviewer Checklist. The HSRO or IRB staff will respond in writing to formal requests for determination of human subjects research status. A copy of the submitted materials and determination correspondence will be kept on file in the VCAA’s Office.

8.2 FDA Determinations

Research activities that involve FDA-regulated drugs, devices, or biologics will be reviewed by the [HSRO](#). If the [HSRO](#) determines that the research falls under [21 CFR 50 & 56](#), the research will be referred to a biomedical IRB with which UIS has established or will establish via an affiliation agreement. The investigator will be instructed that all of the requirements of the affiliated IRB must be complied with and that the IRB Office must be provided with copies of all communications with that IRB. The research conduct and reporting requirements contained in this document will also have to be met for FDA-regulated research.

8.3 Exempt Research

All research using human subjects must be approved by the institution. Certain categories of research (i.e., *exempt research*) do not require full IRB committee review and approval. Exempt research is subject to institutional review and must be determined and approved by the HSRO, by an IRB member designated by the HSRO, or by the Chair of an approved unit or departmental research review committee (see below).

The HSRO or designee will use the IRB Reviewer Checklist to determine and document whether the protocol meets the exemption criteria.

Research with specific populations does not qualify for exemption. See Section 8.3.2 **Limitations on Exemption for Research with Vulnerable Populations**.

It is UIS policy that all exemptions must include a termination date. The period of exemption expires on that date and may not exceed three years. If the researcher intends to extend the project beyond the termination date, the researcher must apply for Continuing Review (Section 7.4).

8.3.1 Approved Departmental or Unit Research Review Committees

Exemption determinations may be conducted at the unit or department level by a registered Research Review Committee for specified types of research. The HSRO must be notified in writing of the research projects approved by departmental or unit research review committees. In order to conduct exemption determinations, departmental reviewers must be well-acquainted with the regulations and, in particular, the criteria for exemptions. Units must submit the qualifications of the departmental reviewers to the HSRO for approval. Training for those reviewers without the necessary qualifications will be provided by the HSRO or GACC. Unit review will follow the same procedures, including submission materials and review checklists, as is described in this section. The HSRO will conduct audits of the unit exemption determinations periodically.

Approved Research Review Committee: is a UIS department or unit research committee formally registered with the UIS Human Subjects Review Officer. Departmental Research Review Committees must renew their registration annually. For more information contact the GACC or equivalent position.

8.3.2 Limitations on Exemption for Research with Vulnerable Populations

Research with vulnerable populations (excluding Pregnant Women, Human Fetuses and Neonates) is exempt from full IRB review when the research involves survey or interview procedures or observations of public behavior when the investigator does not participate in the activities being observed. Also, research involving a broader subject population if the research only incidentally includes prisoners. No other exemptions for research with vulnerable populations apply.

8.3.3 Categories of Research Permissible for Exemption

The categories of research permissible for Exemption are described on the IRB Application for Exemption. The IRB Office staff, IRB members, use the IRB Reviewer Checklist to make a determination.

With the above exceptions (i.e., Section 8.3.2 **Limitations on Exemption for Research with Vulnerable Populations**), research activities in which the only involvement of human subjects will be in one or more of the following categories are *exempt from full IRB review, but require institutional review*, at UIS:

Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as (a) research on regular and special education instructional strategies, *and* (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (a) information obtained is recorded in such a

manner that human subjects cannot readily be identified, directly or through identifiers linked to the subjects; *or* (b) any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; *or* (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review**.

Category 3: Research involving **benign*** behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; *or* (b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; *or* (c) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review**.

[*Note: for the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.]

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category 4: Secondary research for which consent is not required: the study of identifiable private information or identifiable biospecimens, if these sources are publicly available; *or*, if the information, which may include information about biospecimens, is recorded by the investigator in such a manner that subjects cannot readily be identified, directly or through identifiers linked to the subjects. Alternatively, the research is exempt when information collection and analysis involves the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E; *or*, research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501.

Category 5: Research and demonstration projects which are conducted or supported by a Federal department or Agency, or subject to the approval of department or agency heads, and which are 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. Such projects must be conducted pursuant to specific federal statutory authority, there must be no statutory requirements for IRB review, the research must not involve significant physical invasions or intrusions upon the privacy of subjects', and the exemption must be invoked only with authorization or concurrence by the funding agency.

Category 6: Taste and food quality evaluation and consumer acceptance studies, *if* (a) wholesome foods without additives are consumed; *or* (b) 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.

Category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review. If information or biospecimens are collected using a study-specific or registry/biobanking consent (i.e. not meeting all the broad consent requirements), secondary research involving the information or biospecimens can still occur but is not exempt from full IRB review.

Category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (a) broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; (b) documentation of informed consent or waiver of documentation of consent was obtained; (c) the IRB conducts a limited IRB review; *and* (d) the investigator does not include returning individual research results to subjects as part of the study plan.

8.4 Limited IRB Review of Research

Limited IRB review is review conducted using the expedited review procedure on protocols subject to certain exemptions from full IRB review (see 8.3). Unlike expedited review, the criteria for approval of research are based on the terms of the exemption category, rather than the full research criteria.

Protocols approved under the limited IRB review have no continuing review requirement; however, investigators still must comply with the IRB's reporting requirements (for example, modifications to the study or reporting unanticipated problems) and other institutional requirements, policies, and procedures.

8.5 Expedited Review of Research

An IRB may use the expedited review procedure to review any of the following:

(a) some or all of the research appearing on the list of research eligible for expedited review (Section 8.5.1) and found by the reviewer(s) to involve no more than minimal risk ; and

(b) minor changes in research previously approved by the full IRB during the period for which approval is authorized.

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (a) the level of risks to subjects'; (b) the research design or methodology (c) the number of subjects' enrolled in the research; (d) the qualifications of the research team; or (e) the facilities available to support safe conduct of the research. Adding procedures that are not eligible for expedited review (see Section 8.5.1 Categories of Research Eligible for Expedited Review) would not be considered a minor change.

A protocol that has been approved under the expedited review process need not undergo continuing review, unless the expedited reviewer(s) makes a determination that continuing review is needed for protection of human subjects. This determination needs to be documented and include the continuing review interval.

8.5.1 Categories of Research Eligible for Expedited Review

The activities listed below are generally considered to be of minimal risk, and so the activity is eligible for review through the expedited review procedure; however, when the specific circumstances of the proposed research involve more than minimal risk to human subjects, the reviewer must document their determination and make recommendation for a full IRB review. The following caveats also apply:

- The categories listed below apply regardless of the age of subjects', except as noted.
- 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.

UIS IRB Policy

- The expedited review procedure may **not** be used for classified research* involving human subjects.
- The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- Research Categories 1 through 7 pertain to both initial and continuing IRB review.

Category 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 (21 CFR Part 312) is not required*.
- (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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.

[*NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.]

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) from healthy, non-pregnant 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 children¹, 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. [Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."][45 CFR 46.402(a)]

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring 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) un-cannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum-base 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 sub-gingival 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.

Category 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 subjects' 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.

Category 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).

[NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.]

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 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.

[NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.]

Category 8: Continuing review of research previously approved by the full IRB committee 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.

[NOTE: for Categories 8a and 8b the following applicability criteria apply: (1) the remaining activities must be minimal risk; (2) if identification of the subjects' or their responses will reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal; and (3) the research may not be classified research. For Category 8b the only applicability criterion is that the research may not be classified research.

For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of Category 8a, 8b, or 8c are satisfied for that site. However, with respect to Category 8b, while the criterion that "no subjects' have been enrolled" is interpreted to mean that no subjects' have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]

Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where Categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[Under Category 9, an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where Categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting

that the research involves no greater than minimal risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the full IRB committee.]

If a research protocol has been initially approved through a full-board review procedure, the continuing review may not be done by the expedited review procedure unless it falls within Category 8 or 9, above.

8.5.2 Informing the IRB

All members of the IRB will be apprised of all expedited review approvals by means of the agenda for the next scheduled meeting under a section entitled "Staff Report." Copies of the expedited review approvals will be made available for any optional review at the request of any IRB member.

8.6 Full IRB Review

Except when an expedited or limited review procedure is used, the IRB must review proposed research at a full IRB meeting (also known as *Full-Board meetings*) at which a *quorum* (see below) is present. Minutes of each meeting will be kept according to procedures described separately.

8.6.1 Schedule of Full IRB Meetings

In general, regular meetings of the IRB will be scheduled for each semester, and meeting dates will be publicized. The deadline for submission of proposals will be early enough for ORSP staff to screen and compile materials, and IRB members enough time to carefully review the materials. The schedule for the IRB may vary due to holidays or lack of quorum. Special meetings may be called at any time by the Chair of the IRB.

8.6.2 Quorum Requirements

A *quorum* consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area.

8.6.3 IRB Member Conflicts of Interest

IRB members and consultants will not participate in any IRB action taken, including the initial and continuing review of any project, in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A Primary Reviewer with a conflict of interest must notify the GACC or HRSO, who will then re-assign the protocol.

An IRB member is considered to have a conflicting interest when the IRB member or an immediate family member of the IRB member:

- is the project director, or other member of the research team;
- has a financial interest in the research whose value cannot be readily determined or whose value may be affected by the outcome of the research;
- has a financial interest in the research with value that exceeds \$5,000 or 5% ownership of any single entity when aggregated for the IRB member and their immediate family;
- has received or will receive any compensation whose value may be affected by the outcome of the study;
- has a proprietary interest in the research (property or other financial interest in the research including, but not limited to, a patent, trademark, copyright or licensing agreement);
- may be affected by the outcome of the research;
- has received payments from the sponsor that exceed \$10,000 in one year when aggregated for the IRB member and their immediate family;
- is an executive or director of the agency/company sponsoring the research;
- directly supervises or serves on the thesis committee of a student-led project, and/or

- any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

8.6.4 Conflicts of Interest

Active participation by academic staff members in external activities that enhance their professional skills or constitute public service can be beneficial to the University as well as to the individual. Because such activities can lead to conflicts of commitment or interest with regard to one's University responsibilities, the need exists for a general framework against which the propriety and advisability of non-University activities can be measured and monitored.

The University of Illinois Policy on Conflicts of Commitment and Interest (COCI) provides such a framework and identifies procedures for consultation and advice on conflicts of commitment or interest matters, for resolution of situations in which a conflict may exist, and for approval of exceptions when warranted. The Policy makes every effort to balance the integrity and interests of the University of Illinois with the integrity and interests of individual academic staff members. To that end, the Policy attempts not only to identify and eliminate or manage actual conflicts of commitment or interest but, whenever possible, to prevent even the appearance of conflicts. The Policy provides for remedies to manage conflicts constructively and for sanctions when the Policy is violated.

This Policy implements an Illinois law requiring all University staff members to obtain prior written approval before engaging in remunerated private consulting or research for external persons or organizations. It also implements various policies set forth in the University Statutes and The General Rules Concerning University Organization and Procedure. Finally, the Policy accommodates federal regulations designed to protect the integrity of federally funded research.

8.6.5 Protocol-Specific Conflict Management

The IRB application asks protocol-specific questions regarding conflict of interest for the investigators and key personnel. Key research personnel are those individuals who: (a) recruit human subjects; (b) obtain consent from human subjects; (c) collect data from human subjects; *or* (d) evaluate the response of human subjects. When an investigator indicates a financial conflict of interest on the IRB application, a copy of the UIS-approved conflict management plan shall be forwarded to the HSRO. If no approved conflict management plan exists, the IRB will request that the investigator(s) and key personnel work with their unit executive officer to develop one. The IRB protocol will not be reviewed until the conflict management plan is in place.

As part of its review process, the IRB will review the conflict management plan (either at a full IRB meeting or by one or more reviewers as determined by the Chair) and make a determination as to whether the conflict adversely affects the protection of human subjects. If the IRB determines that the conflict does adversely affect human subjects, the conflict management plan must be modified. The IRB has the final authority to decide whether the conflict management plan adequately protects the human subjects and the research can be approved.

Review of conflict management plans are documented in the IRB minutes or in the protocol file for expedited review. If a conflict of interest exists, final IRB approval cannot be given until an approved conflict management plan that adequately protects the human subjects in the protocol is in place.

If the conflict of interest status of an investigator changes during the course of a study, the individual is required to notify the HSRO within ten working days of the change. The IRB will review the change as a modification to the protocol.

At the time of continuing review, the investigator will be asked whether there has been any change in the conflict of interest status relating to the research. The IRB will review conflict of interest as part of its continuing review.

The review and disposition of the conflict management plans are documented in the IRB minutes or, in the case of expedited review, reported to the IRB.

8.6.6 Consent Monitoring

In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer (*Consent Monitor*) is required.

8.6.7 Other Committee Approvals

In the protocol application, the investigator will be asked specific questions to determine if the research requires approval from other pertinent research compliance committees (e.g., a department-level research review committee). If the investigator answers “yes” to any of the questions, then he or she will be requested to provide documentation of approval from the other committees. Final approval from the IRB will be contingent on receipt of the required documentation.

8.6.8 Reporting IRB Actions

All IRB formal actions are communicated to the Responsible Principal Investigator (RPI) and when appropriate, the Responsible Research Supervisor (RRS), or designated primary contact person for the protocol, in writing signed by the HSRO/IRB Chair or designee.

8.7 Continuation Review of Active Protocols

Protocols considered exempt do not undergo continuing review. Certain protocols approved by expedited review do not require continuing review, as described in 45 CFR 46.109. Otherwise the IRB will conduct a continuing review of ongoing research at intervals that are appropriate to the level of risk for each research protocol, but not less than once per year. Continuing review must occur as long as the research remains active for long-term follow-up of participants, even when the research is permanently closed to the enrollment of new participants and all participants have completed all research-related interventions. Continuing review of research must occur even when the remaining research activities are limited to the analysis of private identifiable information.

At UIS, determination of the approval period and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis. For example, for an investigator who is performing research having elevated levels of risk, or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by a subcommittee of the IRB might occur or approval might be subject to an audit of study performance after a few months of enrollment, or after enrollment of the first several subjects’.

For each initial or continuing approval, the IRB will indicate an approval period with an approval expiration date specified. IRB approval is considered to have lapsed at midnight on the expiration date of the approval.

The approval date and approval expiration date are clearly noted on all IRB certifications sent to the RPI and must be strictly adhered to. Investigators should allow sufficient time for development and review of renewal submissions, following the current continuation review procedures.

Review of a change in a protocol ordinarily does not alter the date by which continuing review must occur. This is because continuing review is review of the full protocol, not simply a change to that protocol.

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur by midnight of the date when IRB approval expires.

8.7.1 Expedited Review Procedures

Generally, if research qualified for expedited review at the time of the initial review, it does not need continual review. If an IRB reviewer determines that a minimal risk study requires annual review, the reviewer must explicitly justify why it would enhance the protection of human subjects and document the determination. Such a protocol will qualify for expedited review during continuation review. However, if the review of the additional information collected for the continuation review reveals that the conditions of the research have or will change, the HSRO or designee may initiate a Full IRB Committee review.

8.7.2 Missed Continuation Reviews

The IRB and investigators must plan ahead to meet required continuation review dates. If the IRB has not reviewed and approved a research study by approval expiration specified by the IRB, all research activities must stop, including recruitment (media advertisements must be pulled), enrollment, consent, interventions, interactions, and data collection, *unless* the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. **This will occur even if the investigator has provided the continuation request before the expiration date. Therefore, investigators must allow sufficient time for IRB review before the expiration date.**

8.8 Modification of an Approved Protocol

Investigators may wish to modify or amend their approved applications. **Investigators must seek IRB approval before making any changes in approved research -- even though the changes are planned for the period for which IRB approval has already been given -- unless the change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified within 24 hours).**

When the IRB reviews modifications to previously approved research, the IRB considers whether information about those modifications might relate to participants' willingness to continue to take part in the research and if so, whether to provide that information to participants.

8.9 Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

Federal regulations require organizations to have written policies and procedures to ensure the prompt reporting of unanticipated problems involving risks to subjects' or others to the IRB, appropriate institutional officials, and regulatory agencies. [NOTE: For simplicity, unanticipated problems involving risks to subjects' or others will be referred to as *unanticipated problems* in this policy].

Not all unanticipated problems involve direct harm to subjects'. Events can occur which are unexpected and result in new circumstances that increase the risk of harm to subjects' without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the subjects', individuals the subject may come in contact with, family members, research personnel, etc.) in addition to the subjects'. In each case, while the event may not have caused any detectable harm or adverse effect to subjects' or others, they nevertheless represent unanticipated problems and should be reported promptly.

Events which cause direct harm to subjects' are referred to as *adverse events*. Although adverse events occur most commonly in the context of biomedical research, adverse events can also occur in the context of social and behavioral research. Only unexpected adverse events that are related to the research need to be reported.

8.10 Further Review/Approval of IRB Actions by Others within the Institution

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution; however, those officials may not approve research if it has been not been approved by the IRB. There are no required institutional reviews after the IRB grants approval, but the institution reserves the right to subject research reviewed by the IRB to further review.

8.11 Appeal of IRB Decisions

If the HSRO makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may request appeal by the full IRB committee. If the full IRB committee makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may submit a Request for Reconsideration in writing stating the rationale and providing any additional supporting documentation. The IRB will reconsider the protocol based upon the new information provided. The IRB's determination following reconsideration is final. The investigator may submit a revised protocol for consideration.

8.12 Sponsored Research Contracts

All funded human subjects research must be reviewed and approved by the UIS IRB.

Proposals to be submitted for external funding are sent to the Office of Research and Sponsored Programs along with the Internal Clearance Form. The GACC reviews the compliance checklist on the Internal Clearance Form to determine if the "human subjects" box is checked. If it is checked for human subjects, the GACC reviews the abstract and/or the statement of work to determine if the project involves human subjects. If the human subjects box is not checked, the GACC reviews the abstract or the statement of work to determine if the project involves human subjects and the box should have been checked. If such is the case, the proposal will also be flagged. If it is determined that the proposed research involves human subjects, the Responsible Principal Investigator is notified that if the proposed research is funded, IRB approval must be received prior to opening the grant account.

9.0 Criteria for IRB Approval of Research

In order for the IRB to approve human subjects research, it must determine that the following requirements are satisfied:

1. Risks to subjects' are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects' to risk.
2. Risks to subjects' are reasonable in relation to anticipated benefits, if any, to subjects', and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects' would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects' is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or from the subjects' legally authorized representative, in accordance with, and to the extent required by policy and/or federal regulations.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by policy and federal regulations.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects'.
7. When appropriate, there are adequate provisions to protect the privacy of subjects' and to maintain the confidentiality of data.
8. When some or all of the subjects' are likely to be vulnerable to coercion or undue influence, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects'.

9.1 *Risk/Benefit Assessment*

The goal of the assessment is to ensure that the risks to research subjects posed by participation in the research are justified by the anticipated benefits to the subjects' or society. Toward that end, the IRB must (a) judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies asking any person to undertake the risks; and (b) disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

The assessment of the risks and benefits of proposed research is one of the major responsibilities of the IRB and involves:

- identifying the risks associated with the research, as distinguished from the risks of therapies the subjects' would receive even if not participating in research;
- determining whether the risks will be minimized to the extent possible;
- identifying the probable benefits to be derived from the research;
- determining whether the risks are reasonable in relation to the benefits to subjects', if any, and assess the importance of the knowledge to be gained; and

- ensuring that potential subjects' will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.

9.1.1 Scientific Merit

In order to assess the risks and benefits of the proposed research, the IRB must determine that:

- the research uses procedures consistent with sound research design;
- the research design is sound enough to reasonably expect the research to answer its proposed question; *and*
- the knowledge expected to result from this research is sufficiently important to justify the risk.

For research that is funded externally, the IRB may take into account that the research has been or will be going through a peer review process.

The IRB relies on the knowledge and disciplinary expertise of its members and alternates or consults with other researchers on or off campus for scientific merit review as needed.

9.1.2 Other Considerations

In assessing the benefits of the research, the IRB may also review:

- the qualifications of the research team, including their technical and scientific expertise, as well as their knowledge and understanding of their obligation to protect the rights and welfare of research participants; *and*
- the adequacy of the resources necessary for human research protection, care of research participants, and safety during the conduct of the research.

9.2 Equitable Selection of Subjects

The IRB will review the inclusion/exclusion criteria for the research to ensure equitable selection of subjects'. In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, fetuses, human *in vitro* fertilization, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged (see Section 9.5, Vulnerable Populations).

9.2.1 Recruitment of Subjects

The investigator will provide the IRB with all recruiting materials to be used in identifying participants. The IRB must approve any and all advertisements prior to posting and/or distribution. The IRB will review the:

- information contained in the advertisement;
- mode of its communication;
- final copy of printed advertisements; and
- final audio/video taped advertisements.

This information should be submitted to the IRB with the initial application. The IRB reviews the material to assure that the content is accurate and is not coercive or unduly optimistic, or creating undue influence on the subject to participate.

Any advertisement to recruit subjects' should be limited to the information the prospective subjects' need to determine their eligibility and interest. Advertising should adequately describe the remuneration associated with services as a research subject, but shall not be displayed in such a manner as to emphasize payment as the primary incentive for involvement in the research.

9.3 Informed Consent

The IRB will ensure that informed consent will be sought from each prospective subject or the subjects' legally authorized representative, in accordance with, and to the extent required by policy and federal regulations. In addition, the Committee will ensure that informed consent will be appropriately documented in accordance with, and to the extent required by policy and federal regulations. (See Section 10 below for detailed policies on informed consent).

9.4 Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to protect the privacy of subjects' and to maintain the confidentiality of the data.

9.4.1 Definitions

Privacy: having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality: using effective methods to ensure that information obtained by researchers about their subjects' is not improperly divulged.

Private information: is information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable information: is information through which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

9.4.2 Decision-Making Regarding Invasion of Privacy

The IRB must determine whether the activities in the research constitute an invasion of privacy. In order to make that determination, the IRB must obtain information regarding how the investigators are getting access to subjects' or subjects' information, and consider the subjects' expectations of privacy in the situation. Investigators must have appropriate authorization to access the subjects' or the subjects' information.

9.4.3 Decision-Making Regarding Confidentiality and Anonymity

Confidentiality and anonymity are not the same. If anyone, including the investigator, can readily ascertain the identity of the subjects' from the data, then the research is not anonymous, and the IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of confidentiality protections should be commensurate with the potential of harm from inappropriate disclosure.

9.5 Vulnerable Populations

The IRB will determine whether appropriate additional safeguards are in place to protect the rights and welfare of subjects if they are likely to be members of a vulnerable population (e.g., persons with diminished autonomy). See Section 11.0 **Vulnerable Populations** below for detailed policies on vulnerable populations.

10.0 Informed Consent

10.1 Informed Consent Process

No investigator may involve a human being as a subject in research without obtaining the legally effective informed consent (providing enough information that a reasonable person would want to have) of the subject or the subjects' legally authorized representative unless a waiver of consent has been approved by the IRB in accordance with Section 10.4 **Waiver or Alteration of Informed Consent** of this policy. In general, the IRB considers individuals who are unable to consent for their own clinical care to be unable to consent for research participation.

Investigators must obtain consent *prior* to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.

Consent must always be sought using procedures that (a) provide the prospective subject or the subjects' legally authorized representative sufficient opportunity to consider whether or not to participate; and (b) minimize the possibility of coercion or undue influence.

In determining the appropriateness of the consent process, the IRB will consider:

- the timing and location where the consent process will take place;
- the individual who will be obtaining consent (e.g. the investigator, collaborator, or qualified designee) and his or her training;
- the age, language, literacy, and cognitive capacities of the prospective participant;
- pre-existing role relationships between the researcher and the prospective participant; and
- any factors that might be perceived as coercive or present undue influence to participate in the research.

The IRB will require an alternative process to obtain consent when it determines that a potential subject's understanding of the research may be impaired due to the timing, location, or the individuals participating in the proposed consent process.

The information that is given to a subject or the legally authorized representative must be in language understandable to the subject or the representative.

A person (i.e., a member of the project's research team) knowledgeable about the consenting process and the research to be conducted must obtain the informed consent. If someone other than the investigator conducts the interview and obtains consent, the investigator needs to formally delegate this responsibility. The person to whom the responsibility is delegated must have received appropriate training to perform this activity.

No informed consent, whether oral or written, may include exculpatory language through which a subject or a 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. ([FDA Guidance on Exculpatory Language in Informed Consent](#)).

Exculpatory language: means language in the consent form where the participant in research appears to waive certain legal rights, or to indemnify the researcher in the event the participant is injured.

Indemnify: means to release, or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

10.2 Basic Elements of Informed Consent

Informed consent must be sought from each potential subject or the subjects' legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. The informed consent process must *begin* with key information and that this part of the informed consent be organized and presented in a way that facilitates comprehension.

The basic elements of informed consent are:

1. a statement that the **study involves research**;
2. an explanation of the **purposes** of the research;
3. the **expected duration** of the subjects' participation;
4. a description of the **procedures** to be followed, and identification of any procedures which are experimental;
5. a description of any reasonably foreseeable **risks** or discomforts to the subject;
6. a description of any **benefits** to the subject or to others which may reasonably be expected from the research;

7. when a protocol involves medical or other therapeutic treatments, it must include a disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;
8. a statement describing the extent, if any, to which **confidentiality** of records identifying the subject must be maintained;
9. for research involving more than minimal risk of physical, emotional, or psychological harm, information about the **availability of professional services will be provided**;
10. **contact information** for the person who can answer pertinent questions about the research;
11. **contact information** for the person to notify in the event of a research-related injury to the subject;
12. **contact information** for the HSRO, so that subjects' can report concerns or complaints about the research or obtain answers to questions about their rights as research participants; and
13. **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.**
14. a place for participants to initial, when voice, video, digital, or image recording is involved.
15. a statement about the **future** use of the subject's identifiable private information or biospecimens:
 - Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject; or
 - The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.
16. a statement about the potential for publication or presentation of the study results, and an explanation about how potential identifying information will be managed in those situations.

Additional elements of informed consent to be applied, as appropriate, are as follows:

- **Anticipated circumstances under which the subjects' participation may be terminated by the investigator without regard to the subjects' consent.** The IRB will carefully review the protocol to determine whether there might be situations where participants should be withdrawn from the research, or if it is reasonable to expect that participants may be withdrawn from the research, without their consent. For example, in a dietary study in which the participants have to follow a strict dietary regimen, there is a reasonable likelihood that some participants may not adhere to the regimen. Thus, such a situation might reasonably occur and the termination statement should be added to the consent form.
- **Additional costs to the participant that might result from participation in the research.** Whenever the protocol information indicates a situation in which it is reasonable to expect that subjects' will incur travel or non-travel expenses as a result of participating in the research, an additional cost statement should be included in the consent document. For example, if subjects' are traveling from outside of the immediate area in which they live in order to participate in the research, they are likely to incur gas expenses for which they won't be compensated.
- **Consequences of a participant's decision to withdraw from the research.** A statement indicating any consequences that will be imposed if subjects' end their participation in the research prematurely should be included on all consent documents. For example, any protocol involving UIS students, staff, or faculty as subjects' should indicate that their decision to withdraw from the study will have no effect on their current status or future relations with the University of Illinois. Protocols that involve any form of remuneration (e.g., monetary, gift card, course credit) must include a statement on the consent form indicating whether the subject will still receive the full token, a reduced amount, or nothing if they withdraw from the study.

- **Procedures for orderly termination of participation by the participant.** Consent forms should include an explanation of what will happen to the subjects' data if he or she withdraws from the research (e.g., data will be excluded from the research and destroyed). Such statements are particularly important for protocols involving more than one data collection session or the collection of sensitive information.
- **Risks related to pregnancy.** Information regarding potential risks related to pregnancy is important when a research procedure may pose a risk to an embryo or fetus, but the applicability of the risks may not be apparent at the time of consent. For example, a female subject may not be pregnant at the time of consent but may become pregnant during the data collection or treatment phase of the research. Thus, such a statement would be important and required for MRI studies for which the MRI procedures may or may not pose a risk of harm to a developing embryo or fetus.
- **New findings developed during the course of the research which might affect the subjects' willingness to continue participation.** Research protocols involving multiple data collection phases extending over time can generate preliminary findings that have risk implications for new or continuing subjects'. Subjects' must be informed of any significant findings that might affect their willingness to continue participation, and this is particularly important when the research conditions or procedures involve more than minimal risk of harm to the subjects'.
- **Number of participants involved in the study.** When the number of subjects' is relatively small (10 or less) and the information being collected from the participants is uniquely identifiable in nature, the need to protect confidentiality is particularly acute. Concern about protecting confidentiality is also magnified when data collection involves sensitive information. Under such circumstances, participants should be informed about the number of subjects' expected to participate in the research, procedures taken to ensure confidentiality, and any limitations on the researcher's ability to protect confidentiality.
- **Limitations on the researcher's ability to protect confidentiality.** When research data are collected under group conditions involving oral responses or behavioral observation (e.g., focus or intervention groups), the researcher cannot guarantee confidentiality. Research participants should be informed about the steps the researcher will take to protect confidentiality, but must also be informed of the limitations on the researcher's ability to protect confidentiality.
 - 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.
 - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
 - 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).

10.3 Broad Consent

Broad consent is the seeking of prospective consent from subjects to unspecified future research for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. It is an alternative to the standard informed consent process described in 45 CFR 46.116(d). The UIS IRB currently does not allow the use of this alternative consent method. Investigators are advised to obtain standard consent or apply to the IRB for a waiver of informed consent.

10.4 Waiver or Alteration of Informed Consent

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 for informed consent provided the IRB finds and documents that:

- the research involves no more than minimal risk to the subjects’;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects’;
- the research could not practicably be carried out without the waiver or alteration for access to identifiable information and/or biospecimens; *and*
- whenever appropriate, the subjects’ must be provided with additional pertinent information after participation;

or

- 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 the research could not practicably be carried out without the waiver or alteration.

10.5 Exception of Informed Consent for Screening, Recruiting, or Determining Eligibility

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:

- investigator will obtain written or oral information from the subject; or
- investigator will obtain identifiable private information or identified biospecimens by accessing records or stored identifiable biospecimens.

10.6 Parental Permission and Assent

See Section 11.1.3 Parental Permission and Assent for policies on parental permission and assent in research involving children.

10.7 Surrogate Consent

Unless waived by the IRB, informed consent must be obtained directly from the individual subject. Under appropriate conditions, investigators also may obtain informed consent from a *legally authorized representative* of a subject (surrogate consent). The provision allowing surrogate consent is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who have an impaired decision-making capacity or who are not otherwise competent to provide consent.

The IRB will require investigators to provide evidence of a completed **competency assessment** whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects’. The IRB will assess whether the proposed plan to evaluate capacity to consent is adequate.

If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study. The IRB will evaluate (a) whether the assent of the subjects’ is required, and (b) whether plan for obtaining assent is adequate.

10.7.1 Definition

Legally authorized representative: means an individual or judicial or other body authorized under applicable law or institutional policy to consent on behalf of a prospective subject to the subjects' participation in the procedure(s) involved in the research [45 CFR 46.102(i)].

The Office of General Counsel of the University has determined that, in Illinois, the following meet the definition legally authorized representative and, thus, can give surrogate consent:

- a court appointed guardian of the person.
- a health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) that specifies that the individual also has the power to make decisions of entry into research.

Investigators should consult with the GACC when conducting research outside of Illinois to determine the requirements for a legally authorized representative in the jurisdiction in which the research will occur.

10.7.2 Conditions for Requesting Surrogate Consent

Such consent may be requested and accepted only when the prospective research participant is not competent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements:

1. The practitioner may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
2. Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.

10.8 Documentation of Informed Consent (Signed Consent)

Informed consent must be appropriately documented, in accordance with, and to the extent required policy and federal regulations, as follows:

1. Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. Electronic signatures are allowed.
2. A copy shall be given to the person signing the form.
3. The consent form may be either of the following:
 - (a) a **written consent document** that embodies the elements of informed consent may be read to the subject or the subjects' legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed;

or

- (b) a **short form written consent document** (when the elements of informed consent have been presented orally to the subject or the subjects' legally authorized representative). When this method is used, *all* of the following requirements must be met:
 - i. the format of the short form will conform to the process described in section 10.2 (begin with key information, organized to facilitate comprehension);
 - ii. there must be a witness to the oral presentation;
 - iii. the IRB must approve a written summary of what is to be signed by the subject or representative;
 - iv. the witness must sign both the short form and a copy of the summary;

- v. the person actually obtaining consent must sign a copy of the summary; *and*
- vi. a copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

10.9 Waiver of Documentation of Informed Consent (Waiver of Signed Consent)

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects' if it finds that *either*:

- 1. the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated;
- or
- 2. the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality [NOTE: Subjects' must be asked whether they want documentation linking them with the research, and their wishes must govern. For example, domestic violence research where the primary risk is discovery by the abuser that the subject is talking to researchers.];
- or
- 3. the research presents no more than minimal risk of harm to subjects' and involves no procedures for which written consent is normally required outside of the research context. Procedures such as non-sensitive surveys, questionnaires, and interviews generally do not require written consent when conducted by non-researchers;
- or
- 4. the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide, in the application materials, a written summary of the information to be communicated to the subject, and the IRB will consider whether to require the investigator to provide subjects' with a written statement regarding the research.

10.10 Review and Approval of the Informed Consent Form and Process

The IRB is responsible for the review and approval of the informed consent form prepared by the investigator. The informed consent form must contain all of the required elements and meet all other requirements as described in this section. If the informed consent has been initially prepared by an external entity other than a UIS Responsible Principal Investigator, the IRB needs to ensure that the consent meets all the requirements of this policy.

IRB approval of the consent must be documented through the use of a certification stamp on each page that indicates the expiration date. If the consent form is amended during the protocol approval period, the date on the modified form will be the **original** expiration date.

In the case of federally funded clinical trials, the investigator must post the consent form document for the trials on a publicly available federal website 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. Posting only a single consent form from a single site is required to satisfy the requirement for a multi-site study.

The investigator will obtain the legally effective informed consent of the subject or the subjects' legally authorized representative. IRB staff and IRB board members utilize reviewer checklists that include an element designed to

prompt consideration of this issue. Particular emphasis is placed on this issue to ensure that the assent of any individual under age 18 is accompanied by some form of consent from the child's parent(s) or guardian(s). This is also a focus of concern for any situation where the subject (even if an adult age 18 or over) experiences a cognitive impairment that makes it essential that a guardian serve as a witness to a signature or that a proxy for that individual provides consent. Further guidance on this issue is offered in 45 CFR 46 Subpart D.

The circumstances of the consent process must provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate. The HSRO, GACC, and IRB members utilize a reviewer checklist that includes an element designed to prompt consideration of this issue. The consent process should be carefully detailed on the IRB application. The information provided should detail how each potential participant will have an opportunity to ask questions prior to any signature of consent or other form of agreement when a waiver/alteration of signed consent is sought.

10.10.1 Risk of Coercion or Undue Influence

The circumstances of the consent process must minimize the possibility of coercion or undue influence. In particular, the IRB must determine that there is no coercion or undue influence in relation to the following situations:

Remuneration: The IRB must determine that there is no monetary compensation/gift certificate/prize, or other award or remuneration that is out of proportion to the amount of time and effort that participants would expend during their involvement in the research. This must be carefully assessed to determine whether remuneration might make participation in the study difficult to reject. This would be of particular concern when remuneration is being offered to individuals from vulnerable populations who have minimal financial resources.

Dual Relationships: The researcher(s) should disclose any dual relationship, or potential dual relationship, that might be involved in the research process. Dual relationships of concern exist when the investigator or the individual administering the research is in a position of power or influence over the research subjects for a reason not connected with the research. For example, when the investigators are course instructors or supervisors of the University of Illinois Springfield students who are being recruited to participate in the research, students may feel coerced to participate in the research in order to please the professor and/or avoid retribution related to grading. The same issue would arise when a University of Illinois Springfield researcher is recruiting participation from UIS faculty, staff, or students who are also being supervised by the researcher. Similar relationships could exist in contexts outside the university.

10.10.2 Consent Language

The individuals communicating information to the prospective participant, or to the legally authorized representative, during the consent process must provide the information in language understandable to the participant or representative. The language of the consent form should match the estimated reading level of the participants. For example, challenges in the consent process arise when English is not the first or primary language and when prospective participants have cognitive impairments. The researcher must take reasonable steps to address these challenges. The IRB will assess the adequacy of the steps, in light of the risks of the research to the participants. Whenever the protocol involves a significant number of participants, for whom English is not the primary language, reasonable efforts must be made by the investigator to provide translation services and to offer translated consent documents whenever necessary.

Researchers may request a waiver or an alteration of the signed consent process for vulnerable populations who have cognitive impairments and/or low literacy levels, and provide additional assistance in reading the consent document and understanding the consent process. Options include using oral consent, providing short summary documents of the main consent documents that highlight the important points in a brief manner, etc.

10.10.3 Consent and Language Barriers

Researchers should prepare both English language and translated consent forms for proposals that include non-English-speaking subjects'. An explanation of the translations and evidence of the comparability of the English and non-English consent forms is requested. The IRB may consult with language experts or require a "back-translation" into English. The translation should provide documentation to verify the accuracy of the translation and back-translation.

If a non-English-speaking subject is enrolled unexpectedly, researchers may rely on an oral translation of the English language consent form, but should take extra care in the informed consent process to ensure that the subject has understood the project. A statement in the research records (and on the English language consent form) should indicate that the translation took place, identify the translator, and document the translator's belief that the subject understands the study and the consent process. If the subject is a patient, a note about the translation should be made in the patient's research records as well. Researchers should try to provide a written translation of the vital emergency contact information.

Sometimes a subject understands English but does not read or write English. Again, an impartial witness should document that the subject understands the research and the consent process and consented to participate.

10.10.4 Exculpatory Language

The information communicated to the prospective participant, or the participant's representative, during the consent process may not include exculpatory language through which the participant or the legally authorized representative was made to waive or appear to waive any of the participant's legal rights. There are reviewer checklist items that prompt the HSRO, GACC, and IRB members to review the consent document carefully to make sure that no statement appears on the consent document that waives or appears to waive a participant's legal rights.

The information being communicated to the participant or the legally authorized representative during the consent process may not include exculpatory language through which the participant or the legally authorized representative release the investigator, the sponsor, UIS or its agents from liability for negligence. Research studies involving human subjects that involve more than minimal risk of physical harm (for example, studies that require the participant to engage in moderate or higher levels of physical exercise) may contain the following liability statement. However even this statement makes clear that any legal obligation would be honored if required by law:

The University of Illinois Springfield does not provide medical or hospitalization insurance coverage for participants in this research study nor will the University of Illinois Springfield provide compensation for any injury sustained as a result of participation in this research study, except as required by law.

11.0 Vulnerable Populations

When some or all of the participants in a protocol are likely to be vulnerable to coercion or undue influence, the IRB should include additional safeguards to protect the rights and welfare of these participants. Some of the vulnerable populations that might be involved in research include children, pregnant women, fetuses, neonates, and prisoners, adults who lack the ability to consent, students, employees, or homeless persons.

If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants. For example, the IRB will include one or more individuals who are knowledgeable about or experienced in working with children, prisoners, or adults with limited decision-making capacity, when reviewing research that involves individuals from these populations.

The Department of Health and Human Services (HHS), Code of Federal Regulation, Title 45 Public Welfare, Part 46 Protection of Human Subjects, contains additional safeguards designed to provide extra protections for vulnerable populations. These provisions provide for additional requirements for IRBs. Relevant subparts include:

- Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects'
- Subpart D - Additional Protections for Children Involved as Subjects' in Research

HHS-funded research that involves any of these populations must comply with the requirements of the relevant subparts. In addition, although research funded by other federal agencies may or may not be covered by the subparts, these additional agencies may impose additional requirements for the protection of human subjects in research.

Under UIS's FWA the subparts only apply to HHS-funded research and research funded by another federal agency that requires compliance with the subparts. However, the following policies and procedures, which are based on the subparts, apply to all UIS research regardless of funding. The individual sections describe how the subparts apply to HHS-funded research.

11.1 Research Involving Children

The following applies to all research involving children, regardless of funding source. The requirements in this section are consistent with Subpart D of 45 CFR 46, which applies to HHS-funded research.

11.1.1 Definitions

Child: in Illinois, a *child* is defined as an individual who has not attained 18 years of age. (750 ILCS 36/102) [NOTE: For research conducted in jurisdictions other than Illinois, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The researcher should work with the GACC for assistance with regard to the laws in other jurisdictions.]

Guardian: in Illinois, a *Guardian* of a minor means someone who has the duty and authority to act in the best interests of the minor, subject to residual parental rights and responsibilities, to make important decisions in matters having a permanent effect on the life and development of the minor and to be concerned with his or her general welfare. [NOTE: For research conducted in jurisdictions other than Illinois, the research must comply with the laws regarding guardianship in all relevant jurisdictions. The researcher should work with the GACC for assistance with regard to the laws in other jurisdictions.]

Assent: a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

Permission: the agreement of parent(s) or legal guardian to the participation of their child or ward in research.

Parent: a child's biological or adoptive parent.

11.1.2 Allowable Categories

Research on children must be reviewed and categorized by the IRB into one of the following groups:

Category 1: Research not involving physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., **minimal risk**). [45 CFR 46.404]

- For research in this category, the IRB may find that the permission of one parent is sufficient.

Category 2: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject. [45 CFR 46.405] For research in this category:

- the risk must be justified by the anticipated benefit to the subjects';
- the IRB may find that the permission of one parent is sufficient; *and*
- the assent of the child is required.

Category 3: Research involving greater than minimal risk and no reasonable prospect of direct benefit to the individual subject, but likely to yield generalizable knowledge about the subjects' disorder or condition. [45 CFR 46.406] For research in this category:

- the risk represents a minor increase over minimal risk;
- the intervention or procedure presents experiences to subjects' that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- permission of either both parents, or legal guardian, is required- unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child; *and*

- assent of the child is required.

Category 4: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. [45 CFR 46.407]

- HHS-funded research in this category must be approved by the Secretary of Health and Human Services, and requires consent of either both parents, or legal guardian, unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child. If the IRB determines that the research falls in this category, the research will be sent to OHRP for HHS review.
- For non-federally-funded research, the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, and law). Based on the recommendation of the panel, the IRB may approve the research if:
 1. The research in fact satisfies the conditions of the previous categories, as applicable; or
 2. The following conditions apply:
 - i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
 - ii. The research will be conducted in accord with sound ethical principles; and
 - iii. Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

11.1.3 Parental Permission and Assent

The IRB's determination of whether consent must be obtained from one or both parents will be documented in the letter authorizing the research when a protocol receives expedited review, and in meeting minutes when reviewed by the full IRB committee.

11.1.3.1 Parental Permission

In accordance with 45 CFR 46.408(b), the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parents or guardians.

Permission from both parents is required for all research to be conducted with children unless:

- one parent is deceased, unknown, incompetent, or not reasonably available; or
- only one parent has legal responsibility for the care and custody of the child; or
- the research falls under Categories 1 and 2 above (Section 11.1.2) and the IRB has determined that the permission of one parent is sufficient.

Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(a) and any additional elements the UIS IRB deems necessary.

The IRB may find that **the permission of one parent** is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405 (see Section 11.1.2 Categories 1 and 2, above). Consent from both parents is required for research to be conducted under 45 CFR 46.406 and 45 CFR 46.407 (see Section 11.1.2 Categories 3 and 4, above) unless:

- one parent is deceased, unknown, incompetent, or not reasonably available; or
- when only one parent has legal responsibility for the care and custody of the child.

The IRB may waive the requirement for obtaining consent from a parent or legal guardian if:

- the research meets the provisions for waiver in 45 CFR 46.116(e); and
- the IRB determines that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects' (for example, neglected or abused children), and an appropriate mechanism for protecting the children who will participate as subjects' in the research is substituted, and that the waiver is not inconsistent with Federal State, or local law.

The choice of an appropriate mechanism for consent would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

11.1.3.2 Assent from Children

Because *assent* means a child's affirmative agreement to participate in research, [45 CFR 46.402(b)], the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the IRB is charged with taking into account the ages, maturity, and psychological state of the children involved. The UIS IRB has the discretion to determine children's capacity to assent on a subject group basis (i.e., considering all of the children to be involved in a proposed research activity) or on an individual subject basis. Although the IRB may employ a consultant to help make this determination, the ultimate decision regarding ability to assent will be made by the IRB.

The IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective subjects'. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity levels limit their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree he or she is capable of, what participation in the research would involve.

The IRB presumes that children ages 7 and older should be given an opportunity to provide assent. Generally, oral assent through the use of a script should be obtained from children 7 through 11 years of age. Written assent, using a written document for the children to sign, may be sought for older children.

At times there may be inconsistency between parent permission and child assent. Usually a "no" from the child overrides a "yes" from a parent, but a child typically cannot decide affirmatively to be in research over the objections of a parent. Obviously, there are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life threatening disease is being considered). The general idea, however, is that children should not be forced to be research subjects, even when their parent consent to it.

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

Even when the IRB determines that the subjects' are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in Section 10.3 Waiver or Alteration of Informed Consent.

The Assent Form

Researchers should draft a form that is age-appropriate and study-specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

- tell why the research is being conducted;
- describe what will happen and for how long or how often;
- say it's up to the child to participate and that it's okay to say "no";
- explain if it will hurt and if so, for how long and how often;
- say what the child's other choices are;
- describe any good things that might happen;

- say whether there is any compensation for participating; *and*
- ask for questions.

For younger children, the document should be limited to one page if possible. Illustrations might be helpful, and larger type makes a form easier for young children to read. Studies involving older children or adolescents should include more information and may use more complex language.

11.1.3.3 Children Who are Wards

Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects', but only if it is likely to yield generalizable knowledge about the subject's disorder or condition **and is:**

- (a) related to their status as wards; or
- (b) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects' are **not** wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in *loco parentis*.

The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research **and** who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

11.2 Research Involving Pregnant Women, Human Fetuses and Neonates

The following applies to all research regardless of funding source. Since, according to the UIS FWA, Subpart B of 45 CFR 46 applies only to HHS-funded research, the funding source-specific requirements are noted in the appropriate sections.

11.2.1 Definitions

Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means.

Fetus: the product of conception from implantation until delivery.

Neonate: a newborn.

Nonviable Neonate: a neonate after delivery that, although living, is not viable. See definition of *viable* below.

Pregnancy: the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Viable: as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

11.2.2 Research Involving Pregnant Women or Fetuses

11.2.2.1 Research Not Funded by HHS

For research where the risk to the fetus is no more than minimal and is not funded by HHS, no additional safeguards are required, and there are no restrictions on the involvement of pregnant women.

For research involving more than minimal risk to fetuses and that is not funded by HHS, pregnant women or fetuses may be involved *if all of the following conditions are met*:

1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent under Paragraph 4 or 5 of this Section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; **and**
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

11.2.2.2 Research Funded by HHS

For HHS-funded research, 45 CFR Subpart B applies to all research involving pregnant women.

Under 45 CFR Subpart B, pregnant women or fetuses may be involved in research funded by HHS *if all of the following conditions are met*:

1. Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risk to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent.

5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent under Paragraph 4 or 5 of this Section (**11.2.2.2 Research Funded by HHS**) is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent in Section **11.1.3 Parental Permission and Assent** above;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

11.2.3 Research Involving Neonates

The following policies and procedures apply to all research involving neonates, regardless of funding source.

Neonates of uncertain viability and nonviable neonates may be involved in research *if all of the following conditions are met*:

1. Scientifically appropriate preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements of the following policy section, titled Neonates of Uncertain Viability or Nonviable Neonates, have been met as applicable.

Neonates of Uncertain Viability. Until it has been ascertained whether a neonate is viable or not, a neonate may not be involved in research covered by this subpart **unless the following additional conditions have been met**:

The IRB determines that:

1. the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, **and** any risk is the least possible for achieving that objective; **or** the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means, **and** there will be no added risk to the neonate resulting from the research; **and**
2. the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable Neonates. After delivery, nonviable neonates may not be involved in research covered by this subpart **unless all of the following additional conditions are met**:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; **and**
5. The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

Viable Neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of the IRB Review Process (Section 8.0, above) and Research Involving Children (Section 11.1, above).

11.2.4 Research Involving, After Delivery, the Placenta; the Dead Fetus; or Fetal Material

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus must be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent sections of this manual are applicable.

11.2.5 Research Not Otherwise Approvable

11.2.5.1 Research Not Funded by HHS

If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, and the research is not approvable under the above provisions, then the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on **either** of the following bases:

- (a) that the research in fact satisfies the conditions of Section 11.2.2 (above), as applicable; or
- (b) that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; **and** the research will be conducted in accord with sound ethical principles; **and** informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

11.2.5.2 Research Funded by HHS

HHS-funded research that falls in this category must be approved by the Secretary of Health and Human Services. If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, and the research is not approvable under the above provisions, then the research will be sent to OHRP for HHS review.

11.3 Research Involving Prisoners

Prisoners are another of the three classes that are deemed so vulnerable to exploitation in research that there are special rules protecting them. In the past, prisoners were viewed as a convenient research population. They are housed in a single location, constitute a large and relatively stable population, and live a routine life. Unfortunately, all the things that make prisoners a convenient research population also make prisoners vulnerable to exploitation.

UIS IRB Policy

The concern that 45 CFR 46 Subpart C, and this policy based on Subpart C, attempt to address is whether prisoners have any real choice in participation in research, or whether incarceration prohibits free choice.

The following applies to all research involving prisoners, regardless of funding source. The requirements in this section are consistent with Subpart C of 45 CFR 46, which applies to HHS-funded research.

11.3.1 Applicability

This policy applies to all research conducted under the auspices of UIS involving prisoners as subjects. Even though the UIS IRB may approve a research protocol involving prisoners as subjects' according to this policy, investigators are still subject to the Administrative Regulations of the Illinois Department of Corrections and any other applicable State or local law. [45 CFR 46.301]

11.3.2 Purpose

Prisoners may be under constraints because of their incarceration, which can affect their ability to make a truly voluntary decision to participate as subjects' in research; thus, it is the purpose of this policy to provide additional safeguards for the protection of prisoners involved in research activities. [45 CFR 46.302]

11.3.3 Definitions

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Minimal Risk: 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.

11.3.4 Composition of the IRB

In addition to satisfying the general requirements detailed in the IRB section of this policy (8.0 IRB Review Process), when reviewing research involving prisoners, the IRB must also meet the following requirements:

1. a majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB; and
2. at least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

11.3.5 Additional Duties of the IRB

In addition to all other responsibilities prescribed for IRB in Sections 4.0 through 8.0 of this document, the IRB will review research involving prisoners and approve such research only if it finds **all of the following conditions**:

1. The research falls into one of the following **permitted categories** [45 CFR 46.306]:
 - (a) 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';
 - (b) 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';
 - (c) research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults);
 - (d) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
4. Procedures for the selection of subjects' within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects' must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
5. The information is presented in language which is understandable to the subject population;
6. Adequate assurance exists that the Parole Board will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; **and**
7. Where the IRB finds there may be a need for follow-up examination or care of subjects' after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects' of this fact.

11.3.6 Waiver for Epidemiology Research

The Secretary of HHS has waived the applicability of 45 CFR 46.305(a) (1) and 46.306(a) (2) for certain research conducted or supported by HHS under the following conditions:

1. The research involves epidemiologic studies in which the sole purposes are (a) to describe the prevalence or incidence of a disease by identifying all cases, or (b) to study potential risk factor associations for a disease; **and**
2. The IRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7), **and** determined and documented that (a) the research presents **no more than minimal risk** and no more than inconvenience to the prisoner-subjects', and (b) prisoners are **not** a particular focus of the research.

The specific type of epidemiological research subject to the waiver involves no more than minimal risk and no more than inconvenience to the human subject participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a) (2).

The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the subjects'.

In order for a study to be approved under this waiver, the IRB would need to ensure that there are adequate provisions to protect the privacy of subjects' and to maintain the confidentiality of the data.

11.4 Persons with Mental Disabilities or Persons with Impaired Decision-Making Capacity

Research involving subjects' who are mentally ill or subjects' with impaired decision-making capacity warrants special attention. Research involving these populations may present greater than minimal risk; may not offer direct medical benefit to the subject; and may include a research design that calls for washout, placebo, or symptom provocation. In addition, these populations are considered to be vulnerable to coercion.

The requirements in this section apply to all research involving persons with mental disabilities or persons with impaired decision-making capacity regardless of funding source.

11.4.1 IRB Composition

As needed, consideration may be given to adding another member, or employing a consultant, who is a member of the subject population, a family member of a person within the subject population, or a representative of an advocacy group for the subject population (see Section 5.3 Use of Consultants).

11.4.2 Approval Criteria

Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:

1. Only persons with a mental disability and/or impaired decision-making capacity are suitable as research subjects. Mentally competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include mentally incompetent individuals or persons with impaired decision-making capacity as subjects'. Incompetent persons or persons with impaired decision-making capacity must not be subjects' in research simply because they are readily available.
2. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects' of research that imposes a risk of injury, unless that research is intended to benefit that subject and the potential benefits of participation outweigh any risks.
3. Procedures have been devised to ensure that subjects' representatives are well-informed regarding their roles and obligations to protect incompetent subjects' or persons with impaired decision making capacity. Health care agents [appointed under Durable Power of Attorney for Health Care (DPAHC)] or guardians must be given descriptions of the proposed research studies and the obligations of the subjects' representatives. Health care agents or guardians must be told that their obligation is to try to determine what the subject would do if competent, or if the subjects' wishes cannot be determined, what the health care agent or guardian thinks is in the incompetent person's best interest.

11.4.3 Additional Concerns

Investigators and IRB members must be aware that some subjects' decision-making capacity may fluctuate. For subjects' with fluctuating decision-making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary. **It is the responsibility of investigators to monitor the decision-making capacity of subjects' enrolled in research studies and to determine if surrogate consent must be re-obtained.**

The IRB will require investigators to conduct a **competency assessment** whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects'. The IRB will evaluate whether the proposed plan to assess capacity to consent is adequate.

If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study. The IRB will evaluate whether (a) the assent of the subjects' is required, and (b) the plan for obtaining assent is adequate.

12.0 Complaints, Non-Compliance, and Suspension or Termination of IRB Approval of Research

12.1 Complaints

Complaints reported to the IRB will be evaluated as possible unanticipated problems involving risks to participants or others under Section 7.5.

The HSRO will promptly handle (or delegate to designated staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns, and appeals from investigators, research participants, and others.

12.2 Non-Compliance

All members of the campus community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional policies governing the conduct of research involving human subjects.

12.2.1 Definitions

Non-Compliance is defined as failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB. **Serious Non-Compliance** is defined as failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and that, in the judgment of either the HSRO or the full IRB committee,

increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted without prior IRB approval is considered serious non-compliance.

Continuing Non-Compliance is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or full IRB committee, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

Allegation of Non-Compliance is defined as an as-yet unproved assertion of non-compliance.

Finding of Non-Compliance: is an authoritative determination that non-compliance has occurred. The determination can be supported by a finding of fact or by investigator self-report of non-compliance.

12.3 Suspension or Termination

Suspension of IRB approval is a directive of the full IRB committee or HSRO to temporarily or permanently stop some or all previously approved research activities. Suspended protocols remain open and require continuing review. Termination of IRB approval is a directive of the full IRB committee to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

12.4 Reporting

Serious or continuing non-compliance with regulations or the requirements or determinations of the IRB, and suspensions or terminations of IRB approval, will be reported to the appropriate regulatory agencies and institutional officials according to the Reporting to Regulatory Agencies and Institutional Officials procedures.

Failure to secure necessary UIS IRB approval before commencing human subject research must be reported by the IRB to the appropriate Dean and the Vice Chancellor for Academic Affairs for disciplinary action.

Investigators should also be aware that, in general, UIS **indemnifies** them from liability for adverse events that may occur in UIS studies approved by the UIS IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator **personally liable** in such cases.

12.5 Other Possible Sanctions or Actions

A finding of serious or continuing non-compliance may also result in the following sanctions, among others:

1. Individual **disciplinary action** of the investigator or other personnel involved in a study, up to and including dismissal, pursuant to University policies and procedures.
2. Sponsor actions. In making decisions about supporting or approving applications or proposals covered by this policy, the Department of Health and Human Services or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension as described above, and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department of Health and Human Services or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects. Institutional or individual action by the federal OHRP. The OHRP may:
 - (a) withhold approval of all new UIS studies by the IRB;
 - (b) direct that no new subjects' be added to any ongoing studies;
 - (c) terminate all ongoing studies, except when doing so would endanger the subjects'; and/or

- (d) notify relevant state, federal, and other interested parties of the violations.

13.0 Reporting to Regulatory Agencies and Institutional Officials

The IRB office will initiate the reporting procedures as soon as the IRB (a) determines that an event may be considered an unanticipated problem involving risks to participants or others; (b) determines that non-compliance was serious or continuing; or (c) suspends or terminates approval of research.

14.0 Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the creation of a Privacy Rule for identifiable health information. The resulting Privacy Rule, finalized in August 2002, set a compliance date of April 14, 2003. While the main impact of the Privacy Rule is on the routine provision of and billing for health care, the Rule also affects the conduct and oversight of research. Researchers, IRB staff and members, as well as research administration must be aware of these policies.

14.1 Historical Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is an expansive federal law, only part of which is intended to protect the privacy of health care information. HIPAA required Congress to enact a health information privacy law by August 1999 and stated that if it did not act by then, which it did not, the U. S. Department of Health and Human Services (HHS) must develop privacy regulations. The final Privacy Rule was published on August 14, 2002. The objective of the rule is to protect the privacy of an individual's health care information. It creates a federal "floor" of protection so that everyone in the U.S.A. has the same basic rights and protections, though some may have additional rights depending on state law.

14.2 Effects of HIPAA on Research

The final Privacy Rule published on August 14, 2002 included a number of changes in how the Rule applies to research. See the NIH HIPAA Privacy Rule Booklet for Research and the NIH fact sheet on Institutional Review Boards and HIPAA for more information on how HIPAA applies to research. See also Impact of the Privacy Rule on Academic Research, a white paper published by the American Council on Education.

UIS is not a covered entity under HIPAA. However, researchers who are working with "Protected Health Information" (PHI) from other institutions that are covered entities will need to comply with the rules on HIPAA.

14.3 Research under HIPAA

The HIPAA definition of research is identical to the definition provided in the Common Rule: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." HIPAA describes privacy standards for protecting PHI and so only applies to research that involves humans' health information; it does not apply to non-human animal research.

14.4 HIPAA and New Documentation Requirements

New research documents include a HIPAA authorization form, a waiver of authorization form, and a de-identification form. These documents must be used whenever PHI of a covered entity is being utilized in the research.

14.5 Patient Rights and Research

Under HIPAA, patients have certain rights. Those that may affect research include the right to receive a Notice of Privacy Practices; the right to access, inspect, and receive a copy of one's own PHI; the right to request an amendment to one's own PHI; and the right to an accounting of certain disclosures of PHI that occur outside the scope of treatment, including payment and health care operations that have not been authorized.

14.6 HIPAA and Existing Studies

Any research subject enrolled in a study that uses PHI from a covered entity must sign a HIPAA-Compliant Authorization Form. This form is in addition to the existing Informed Consent document, and is federally required. In a few cases, the Informed Consent document may be combined with a HIPAA Authorization.

14.7 Waivers to HIPAA Authorization Form

In some cases an IRB may approve a waiver to use of the HIPAA Authorization Form. This may occur when the IRB finds that (a) the research could not be practically conducted without the waiver, (b) the research could not be practically conducted without access to and use of the PHI, and (c) disclosure poses minimal risk to privacy. This waiver generally comes from the IRB of the covered entity that has ownership of the PHI.

15.0 Special Topics

15.1 Certificate of Confidentiality

Certificates of Confidentiality constitute an important tool to protect the privacy of research subjects. Certificates are issued by the National Institutes of Health (NIH) and other HHS agencies (such as the Centers for Disease Control and Prevention, and the Food and Drug Administration) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Certificates of Confidentiality may be granted for studies collecting information that if disclosed could damage their financial standing, employability, insurability, or reputation or have other adverse consequences for the subjects'. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects'. Contact the Office of Research and Sponsored Programs (ORSP) to discuss further if needed.

The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects'). Certificates of Confidentiality protect subjects' from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects (see Section 15.1.2 Limitations below).

Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered "sensitive" if it involves the collection of:

- information about sexual attitudes, preferences, practices;
- information about personal use of alcohol, drugs, or other addictive products;
- information about illegal conduct;
- information that could damage an individual's financial standing, employability, or reputation within the community;
- information in a subjects' medical record that could lead to social stigmatization or discrimination;
- genetic information;
- tissue samples; or
- information about a subjects' psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the ORSP for help in applying for a certificate.

Certificates are granted sparingly. The study's funding source, if any, is not relevant to the decision. The IRB may *require* investigators to apply for a Certificate of Confidentiality.

15.1.1 Statutory Basis for Protection

Protection against compelled disclosure of identifying information about subjects' of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(d): "The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

15.1.2 Limitations

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research subjects only from legally compelled disclosure of their identity. It does not restrict voluntary disclosures.

For example, a Certificate does not prevent researchers from voluntarily disclosing to appropriate authorities such matters as child abuse or a subjects' threatened violence to self or others, or from reporting a communicable disease. However, if researchers intend to make such disclosures, this should be clearly stated in the informed consent form that research subjects are asked to sign.

In addition, a Certificate of Confidentiality does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if:

- the subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
- authorized personnel of the Department of Health and Human Services (HHS) request such information for audit or program evaluation, or for investigation of HHS grantees or contractors and their employees; or
- release of such information is required by the Federal Food, Drug, and Cosmetic Act or regulations implementing that Act.

15.2 Mandatory Reporting

While any person may make a report if they have reasonable cause to believe that a child or elder was abused or neglected, Illinois law mandates that certain persons who suspect child or elder abuse or neglect report this to the Illinois Department of Children and Family Services (DCFS) or the Illinois Department on Aging, as appropriate.

UIS policy requires the solicitation of informed consent from all adult research subjects, and assent from children involved as research subjects in addition to the consent of their parents. In situations where conditions of abuse or neglect might be revealed, mandated reporters should make themselves known as such to parents of children under age 18, to subjects' who are children, and to subjects' who are potential victims of elder abuse or neglect.

In Illinois state law, the Abused and Neglected Child Reporting Act (<http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1460&ChapterID=32>) and the Elder Abuse and Neglect Act (<http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1452&ChapterID=31>), include "personnel of institutions of higher education" as mandatory reporters.

The University has adopted a policy to implement the Abused and Neglected Child Reporting Act provisions: <https://www.uis.edu/humanresources/policies/policies/protection-of-minors/>

Investigators should consult these sources for more information about mandatory reporting requirements.

15.3 Oral History

The following is based on guidance received from OHRP:

Determining whether oral history or other activities solely consisting of open-ended, qualitative-type interviews are subject to the policies and regulations outlined in an institution's FWA and HHS regulations for the protection of human research subjects (45 CFR 46) is based on the prospective intent of the investigator and the definition of *research* under HHS regulations at 45 CFR 46.102(l) (i.e., "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge").

For the purposes of this policy, the evaluation of such activities specifically focuses on determining whether:

- (a) the activity involves a prospective research plan that incorporates data collection (including qualitative data) and data analysis to answer a research question; and
- (b) the activity is designed to draw general conclusions (i.e., knowledge gained from the study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

In order to be subject to the University of Illinois Springfield's human research protections policies, the activity must meet both of the above standards. This determination will be made according to the procedures described in **Section 8.1 Human Subjects Research Determination** above.

15.3.1 General Guidelines for Evaluating Oral History Activities

Guideline 1: Oral history activities, such as open ended interviews, that **only** document a specific historical event or the experiences of individuals **without** intent to draw conclusions or generalize findings would **not** constitute research as defined by HHS regulations 45 CFR part 46.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does not intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

Guideline 2: Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) constitute research as defined by HHS regulations at 45 CFR part 46.

Example: Conduct an open ended interview of surviving Gulf War veterans to document and to draw conclusions about their experiences, inform policy, or generalize findings.

Guideline 3: Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive constitutes research under 45 CFR part 46.

Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

Investigators are advised to consult with the HSRO or GACC as needed to determine whether their oral history activities meet the definition of research with human subjects as outlined in this policy and require IRB review.

15.4 Genetic Studies

Genetic research studies may create special risks to human subjects and their relatives. These involve medical, psychosocial, and economic risks, such as the possible loss of privacy, insurability, and employability; change in immigration status; and limits on education options, and may create a social stigma. Knowledge of one's genetic make-up may also affect one's knowledge of the disease risk status of family members.

In studies involving genetic testing, several questions need to be addressed, including:

- Will individual test results be given?
- Will disease risk be quantified, including the limits on certainty of the testing?
- Will a change in a family relationship be disclosed, such as mistaken paternity?
- Does the subject or family member have the option not to know the results? How will this decision be recorded?
- Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
- Do any practical limitations exist on the subjects' right to withdraw from the research, withdraw data, and/or withdraw DNA?
- Is the subject permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?

For DNA banking studies, several additional questions need to be addressed, including:

- Will DNA be stored or shared? If shared, will the subjects' identity be known by the new recipient investigator?
- Will the subject be contacted in the future by the investigator to obtain updated clinical information?
- How can the subject opt out of any distribution or subsequent use of his/her genetic material?

15.5 Research Involving Coded Private Information or Biological Specimens

UIS policy is based on the OHRP guidance document entitled *Guidance on Research Involving Coded Private Information or Biological Specimens*. This document:

- provides guidance as to when research involving coded private information or specimens is or is not research involving human subjects, as defined under HHS regulations for the protection of human research subjects ([45 CFR part 46](#));
- reaffirms OHRP policy that, under certain limited conditions, research involving **only** coded private information or specimens is not human subjects research; and
- provides guidance on who should determine whether human subjects are involved in research.

15.5.1 Definitions

For purposes of this policy, *coded* means that: (a) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (b) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Under the definition of *human subject* in Section 2 of this policy, *obtaining* identifiable private information or identifiable specimens for research purposes constitutes human subjects research. This includes an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

Obtaining: means receiving or accessing identifiable private information or identifiable specimens for research purposes.

In general, private information or specimens are considered to be individually identifiable when they can be linked to specific individuals by the investigator(s), either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Research involving **only** coded private information or specimens do **not** involve human subjects if the following conditions are both met:

- (a) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**
- (b) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - (i) the key to decipher the code is destroyed before the research begins;
 - (ii) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased [NOTE: that the HHS regulations do not require the IRB to review and approve this data use agreement];
 - (iii) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; **or**
 - (iv) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited in 2(a)-(d) above may (a) unexpectedly learn the identity of one or more living individuals, or (b) for previously unforeseen reasons now believe that it is important to identify the individual(s). If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity now would involve human subjects. Unless this human subjects research is determined to be exempt (See Section 8.3 Exempt Research), IRB review of the research would be required. Informed consent of the subjects' also would be required unless the IRB approved a waiver of informed consent (See Section 10.3 Waiver or Alteration of Informed Consent).

15.5.2 Determining Whether Coded Private Information or Specimens Constitute Human Subjects Research

The investigator in consultation with the Human Subjects Review Officer will determine if the research involving coded information or specimens requires IRB review. If the request is verbal (by phone or in person) or by email, it is the investigator's responsibility to maintain documentation of such a decision. If the investigator submits a formal submission, the request must include sufficient documentation of the activity to support the determination. Formal submissions will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file.

15.6 International Research

Research with international subjects requires sensitivity, as different cultural contexts may indicate certain classes of people are more vulnerable to being coerced or influenced to participate in human subjects research. There may also be increased risks to breaches of confidentiality or the consequences of such a breach. Therefore it is recommended

that the IRB seek the expertise of someone familiar with the culture of the country where the investigator is proposing to conduct research.

Additional considerations when conducting international research include ensuring that all consent documentation are translated into the native language of the target population. The monitoring plan needs to include someone in-country for subjects to contact with their questions and concerns.

Finally, the investigator needs to be aware of local laws which may limit contact with subjects or indicate different privacy regulations than what are expected in the United States. For example, people residing in the European Union Economic Area (EEA) have rights in the *General Data Protection Regulations* (GDPR) which determine what is considered private information and how a researcher can collect, transport, analyze, and share personal data.

16.0 References

Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the *Belmont Report*; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979. (<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>))

Federal Policy for the Protection of Human Subjects. U.S. Department of Health and Human Services (HHS) policies and regulations at 45 CFR 46, the “Common Rule”). (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>)

Food and Drug Administration (FDA) regulates experiments involving a test article with one or more human subjects that either is subject to requirements for prior submission to the FDA under Section 505(i) or 520(g) of the Act, or is not subject to requirements for prior submission to the Food and Drug Administration under these Sections of the Act. The results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58, regarding non-clinical laboratory studies. An experiment, as defined in 21 CFR 312, includes any use of a drug other than the use of a marketed (approved) drug in the course of medical treatment.

Institutional Review Board Member Handbook in its latest edition (see Amdur & Bankert, 2007).

General Data Protection Regulation (6 Apr 2016 <http://data.consilium.europa.eu/doc/document/ST-5419-2016-INIT/en/pdf>)

Guidance on Research Involving Coded Private Information or Biological Specimens (August 10, 2004 <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>).

Guidance on Certificates of Confidentiality (25 Feb. 2003. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/certificates-of-confidentiality/index.html>)

National Institutes of Health (NIH) policy on “Use of a Single Institutional Review Board for Multi-Site Research”

Payments to Human Subjects. Office of Business and Financial Services (15 Nov. 2017. <https://www.obfs.uillinois.edu/bfpp/section-8-payments-reimbursements/payments-human-subjects>)

UIS Policy on Policies (11/1/12) <https://www.uis.edu/academicstaffhandbook/university-policies/policy-on-policies/>

University of Illinois Policy on Conflicts of Commitment and Interest (7/19/2018) https://www.vpaa.uillinois.edu/rnua/coci_policy

Appendix:

UIS IRB Policy

UIS IRB Policy Glossary