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1.0 MISSION

The University of Indianapolis (UIndy), through ethical review and regulatory compliance, promotes and protects the rights and welfare of all stakeholders in human subjects research conducted by or under the auspices of the University. UIndy will promote and protect the well-being of all stakeholders—individual participants, investigators, institutions, and the integrity of research—by reviewing all human subjects research and certifying that the conduct of human subjects research complies with local values, state laws, the principles of respect for persons, beneficence, and justice, as set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report), and the regulations and guidance promulgated and enforced by the Office for Human Research Protections (OHRP) within the Department of Health and Human Services (HHS). UIndy will comply with OHRP regulations set forth within the Code of Federal Regulations (CFR) at 45 CFR 46., and the Federal Policy for the Protection of Human Subjects (also known as the “Common Rule”). For the purposes of this policy, all references to the Common Rule will cite the regulations in 45 CFR 46.

To fulfill this responsibility effectively, UIndy maintains a registered Institutional Review Board (IRB) to review research protocols involving human participants and to evaluate both risk and protection against risk for those participants. It is the function of the IRB to:

1. determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth in the Common Rule regarding the health, welfare, safety, rights, and privileges of human participants; and
2. assist the investigator in complying with Federal and State regulations by providing campus-wide IRB education and consultation.

More specific information regarding the UIndy IRB’s mission is available in its charter.

1.1 INTRODUCTION

The University of Indianapolis Policies and Procedures for the Protection of Human Subjects Manual (i.e., Manual) details the policies and regulations governing research with human participants and the requirements for submitting research proposals for review by the IRB. These policies and procedures apply to all research involving human participants, regardless of sponsorship and performance site, if UIndy faculty, staff, students, or facilities are involved.

This version of the Manual presents the most current information for reference by potential investigators and their staff. Since the field of human research protections is constantly evolving, sections of the manual are subject to change without prior notification. The Office of the IRB Director and Human Protections Administrator (HPA) will keep the UIndy community apprised of all developments. For further information, contact the Office of the IRB Director at (317) 781-5774.
1.2 ETHICAL PRINCIPLES: THE BELMONT REPORT

It is the duty of the IRB to review and make decisions on all protocols for research involving human participants. The primary responsibility of the IRB is the protection of research participants from undue risk and from deprivation of personal rights and dignity. This protection is best assured by adherence to the following three ethical principles:

1. Respect for Persons
2. Beneficence
3. Justice

Respect for Persons
One of the most important elements in any research involving human participants is the assurance of voluntary informed consent. People, who are potential research participants, whether designed for their own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what is to be done and what potential risks and benefits may be incurred as a result of participation. People must give consent freely, without pressure or inappropriate inducement. The IRB strives to ensure voluntary informed consent of research participants through careful review of the recruitment and consent processes and all related documentation.

When potential research participants are unable to give legal consent, the consent document is addressed to those who have been designated legally responsible for the research participant’s well being (e.g. parents/guardians of children). In all situations, the IRB’s concern is to verify that the consent processes and documents are likely to assist potential research participants in the process of informed decision making. 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 participants. The IRB must exercise special care when considering participants whose ability to give free and informed consent may be compromised in any way.

Beneficence: The Risk-Benefit Ratio.
The IRB is charged with deciding, for any proposed activity which 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 risk/benefit 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. When reviewing research proposals, the IRB committee members must carefully evaluate the types and degrees of risks and benefits for a given participant population. Additionally, the IRB committee members must evaluate the investigator’s communication of these risks and benefits (as described in the consent process and Informed Consent document).
The design of the study must be sound in order to derive scientific benefit. While the IRB is not charged with reviewing scientific design per se, the design must sometimes be considered by IRB committee members as they evaluate the likelihood of research related participant risk and benefit. If a study design is inadequate to attain the stated purpose of the research, then no benefit can be anticipated from conducting the study. In the absence of benefit, there is no justification for placing any research participant at risk, however minimal.

**Justice: The Fair Selection of Research Participants.**
Both the risks and the potential benefits of research should be distributed fairly among potential individual research participants and research participant groups. Study design and selection of participants should avoid bias for or against particular social, racial, sexual, or ethic groups.

The guiding principle in the ethical selection of research participant groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus participant 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 participant population. In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations. Investigational drugs are usually tested in adults before they are tested in children. Certain investigational drugs and procedures may be tested in healthy volunteers before they are tested in patients.

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 participant groups, the results of some trials were of questionable value for members of other social, racial, sexual, 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 participants as feasible and the data be analyzed to uncover responses that differ between groups. Where 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.
2.0 Definitions

Adverse Event - Any untoward or unfavorable physical or psychological occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research (http://www.hhs.gov/ohrp/policy/advevntguid.html).

Assent - Affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

Benefit - Something that promotes or enhances well-being; an advantage

Certification - The official notification by the University to the supporting 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.

Child/Children - Stage of human development that spans the ages of newborn to 19 years. Because children may not have the developmental capacity to understand participation in research, they are considered a vulnerable population. Moreover, because some state jurisdictions set the age of majority (i.e., legal authority to consent and participate as an adult) children may also be legal minors, as and such are a vulnerable population. Residents under 18 years of age are considered minors in Indiana, unless they are "emancipated" by court order.

Confidentiality - Procedures used to prevent unauthorized disclosure of private information investigators obtain from and/or about living human beings. The purpose of confidentiality procedures is to protect the privacy of research participants.

Conflict of Interest - A set of conditions in which an individual’s judgment concerning a primary interest (e.g., subject welfare, integrity of research) could be biased by a secondary interest (e.g., personal or financial gain).

Engaged/engagement - An institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. Institutions engaged in non-exempt human subjects research MUST conduct IRB review BEFORE initiating the research. For additional information see: http://www.hhs.gov/ohrp/policy/engage08.html#

Exempt Research - Human subjects research that is not eligible for IRB review. The federal regulations specify six categories of exemption eligible research METHODS (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101). The Human Protections Administrator has the authority to review and approve exempt research.
Expedited Review (Procedures) - Regulatory review procedures the IRB may use for human subjects research the risks of which do not exceed the “minimal risk threshold” (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110). Expedited procedures do not require full IRB review.

Federal Regulations - Federal administrative law serving as policy to protect the rights and welfare of those who participate as subjects, investigators or other stakeholders in the conduct of human subjects research. The Office for Human Research Protections (OHRP) regulations are codified in the Federal Code of Regulations (CFR) at 45 CFR 46. The OHRP regulations have various subparts. Subpart A, known as the “Common Rule” because several federal agencies must follow these regulations.

Federalwide Assurance of Protection for Human Subjects (FWA) - An agreement or promise between the institution and the Office for Human Research Protections (OHRP), on behalf of the Secretary of the Department of Health and Human Services (HHS) stipulating the method(s) by which the institution will protect the rights and welfare of research subjects in accordance with federal regulations. The FWA, approval of which is a condition of receipt of DHHS support for research involving human subjects, specifies the institution’s responsibilities for meeting the requirements of 45 CFR 46.

Generalizable Knowledge - Knowledge that describes and/or explains testing and/or developing of hypotheses and/or theories, answers study questions, and/or draws conclusions about populations and/or circumstances beyond the research context. The intent to contribute or develop generalizable knowledge is a definitional criterion of the term “research.”

Guardian - An individual who is authorized under applicable state or local law to consent on behalf of a child or other individual who is legally/judicially incompetent to consent to participate in research activities. A guardian may function as a legally authorized representative to consent to participation in research activities.

Human participant (subject) - A living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

Human Protections Administrator (HPA) - Individual authorized by the Institutional Official and/or other institutional authorities and designated on the Federalwide Assurance (FWA) to oversee human protections programming and compliance.

Human Subjects Research - For the purposes of this policy, “human subject research” is defined in 45 CFR 46.102(f) as systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge by collecting and analyzing data about living human beings obtained via interaction and/or intervention OR collection of private, identifiable information (e.g., data base).

Informed Consent - Participant’s verbal and/or non-verbal voluntary approval to participate in a research study after achieving an understanding of the risks and benefits of participation. This
terms also denotes the process by which investigators convey information, confirm comprehension, and document participant’s voluntary consent to participate.

**Interaction** - Any communication or interpersonal contact between investigator(s) and research subject(s). Examples include telephone conversation, email, interview, and online survey.

**Intervention** - Physical procedures by which data are gathered [example, blood samples, biometric devices (e.g., FitBit), etc.] and manipulations of the subject or the subject's environment (e.g., exercise studies, cognitive tasks, etc.) that are performed for research purposes.

**IRB** - An Institutional Review Board established in accord with and for the purposes expressed in this policy.

**IRB approval** - 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.

**Legally authorized representative** - An individual authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. Examples include guardian, attorney-in-fact with authorizations specified in a power-of-attorney, health care representative or surrogate/proxy decision-maker authorized by jurisdiction in which the consent is sought.

**Minimal risk** - 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. For research involving prisoners, "minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**Minor** - Individual under the age of majority as determined by applicable state law.

**Non-compliance** – Failure to conduct human subjects research according to IRB reviewed and approved procedures. Non-compliance may be a protocol deviation or violation. An example of a protocol deviation is a minor adjustment/alteration of data collection procedures to accommodate participant convenience (e.g., scheduling a test outside of the approved timeframe). An example of a violation is substantive and serious revision or omission of an IRB-approved procedure (e.g., failure to have participant sign and date the informed consent document).

**Office of Human Research Protections (OHRP)** - An administrative unit within the Department of Health and Human Services which provides guidance to IRB members, as well as scientists and research administrators, on the complex ethical issues relating to the use of animals and human subjects in biomedical or behavioral research. OHRP also has a regulator rule. OHRP monitors and evaluates an institution’s compliance with the rules governing research subjects.
Furthermore, OHRP has the authority to investigate and, if necessary, to require corrective action or even suspend HHS funding to an institution until the problems are resolved.

**Pregnancy** - Encompasses 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.

**Principal Investigator** - The person with overall responsibility for the conduct of a research study.

**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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

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

**Protocol** - A detailed plan of a scientific or medical experiment, treatment, or procedure

**Protocol Suspension** - IRB approval is put on hold either temporarily or permanently because the protocol no longer fulfills the criteria for IRB approval

**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.

For the purpose 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. Investigations 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.

**Risk** – The magnitude of the potential harm or discomfort and the probability of the harm or discomfort occurring.
3.0 INSTITUTIONAL AUTHORITY

The President of UIndy has designated the Executive Vice President and Provost as the responsible official for carrying out the University’s human research protections program (i.e., Institutional Official; IO). The IO may delegate certain responsibilities in order to maximize efficient and effective IRB review. The IO will delegate responsibilities in accordance with draft guidance promulgated by the Secretary’s Advisory Committee on Human Research Protections (SACHRP; http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html#).

The UIndy IRB has jurisdiction over all non-exempt human subject research that engages UIndy. UIndy adheres to the definition of “institutional engagement” as set forth in OHRP guidance (http://www.hhs.gov/ohrp/regulations-and-policy/guidance/determining-when-institutions-are-engaged-in-research/index.html). Research that engages UIndy includes research conducted on the premises and/or within the facilities of UIndy, conducted by or under the direction of any agent (e.g., faculty, student, etc.) in connection with his or her institutional responsibilities, or involving the use of non-public information to identify or contact human subjects.

3.1 ASSURANCE OF COMPLIANCE

UIndy holds a Federalwide Assurance (FWA), FWA00008582, that OHRP as approved. The FWA assures OHRP that UIndy will protect and the rights and welfare of all stakeholders involved in human subjects research, irrespective of federal involvement.

3.2 UNIVERSITY OF INDIANAPOLIS IRB

The UIndy IRB reports directly to the IO and/or the IO’s designee, and is managed by the IRB Director/HPA. The IRB Director/HPA has expert knowledge of regulatory issues and expert skills in management of human research protections programming. The IRB Director/HPA serves as the primary point of contact at UIndy for OHRP, other regulatory bodies, and local entities.

3.3 STATE LAW

UIndy and its components, including the IRB, rely on the University General Counsel for the interpretations and applications of Indiana State law as it applies to human research protections.

3.4 EXEMPT RESEARCH

UIndy requires institutional review of all human subjects research. Research that satisfies exemption criteria does not require IRB review; however, the HPA will conduct review in order to certify exemption determination. The HPA will certify the exemption determination via a letter to the Principal Investigator. The HPA will report determinations in the IRB minutes.
Exempt research, once approved, is non-renewable. The duration of study for exempt research is limited to that specified on the approved application.

3.4.1 LIMITATIONS OF RESEARCH SUBJECTS

Vulnerable Populations:

- **Children:** Exemption for research involving survey or interview procedures or observations of public behavior does NOT apply, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. (See Section 10.1.1 for the definition of a child)
- **Prisoners, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged:** exemptions do NOT apply. IRB review is required.

If the answer to any of the following questions is no, the research requires IRB review:

- Will the research use only data or specimens that are existing (i.e., collected – “on the shelf” – prior to the beginning of this research project for a purpose other than the proposed research)?
- Are those data or specimens publicly available?
- Will information be recorded by the investigator in such a way that it cannot in any way be linked to the subject?

### 3.4.2 CATEGORIES OF EXEMPTION ELIGIBLE RESEARCH

UIndy requires review and approval of exemption status, and has authorized the HPA to review and approval all exempt-eligible human subjects research. With the above exceptions, research activities in which the only involvement of human subjects will be in one or more of the following categories MAY be exempt from IRB review: University of Indianapolis:

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

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if:

   a) the human subjects are elected or appointed public officials or candidates for public office; or
   b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

5. Research and demonstration projects which are conducted by or subject to the approval of Federal 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.

6. Taste and food quality evaluation and consumer acceptance studies:

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

3.4.3 ADDITIONAL PROTECTIONS

Although exempt research is not within IRB jurisdiction, UIndy expects nonetheless that investigators will conduct exempt research according to all institutional requirements, state and local laws, and the ethical principles of the Belmont Report. The HPA may require additional protections for subjects in keeping with the guidelines of the Belmont Report.
4.0 UNIVERSITY OF INDIANAPOLIS IRB

The IRB is an administrative body established to protect the rights and welfare of stakeholders in human subjects research that engages UIndy. UIndy has established and authorized the IRB to review, approve, disapprove, or require changes in non-exempt research activities involving human subjects. The IRB has been established in accordance with the requirements of current federal rules.

UIndy will review the activity of the IRB on an annual basis and make a determination as to the appropriate number of IRBs for the University.

4.1 AUTHORITY OF THE IRB

The IRB at the University of Indianapolis reviews and has authority to approve, require modifications in, or disapprove all research activities conducted under the auspices of the University. The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB has the responsibility to ensure human research protection review of all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, the consent/assent document(s) and, for studies conducted under the Investigational New Drug (IND) regulations, the investigator's brochure are examples of documents that the IRB should review. The IRB should also review the methods and material that investigators propose to use to recruit subjects.

Before any human subject is involved in research in relationship to the University, an IRB will give proper consideration to:

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

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, pregnant women, 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.

The IRB has the authority to suspend, place restrictions, 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 unexpected adverse events. The IRB has the authority to observe or have a third party observe the consent process and the research activities.

### 4.2 JURISDICTION OF THE IRB

IRB jurisdiction extends to ALL non-exempt research (funded and not funded) involving human subjects engaging UIndy. However, in the event UIndy personnel are conducting human subjects research in cooperation with another engaged institution, UIndy may elect to execute an Authorization/Reliance Agreement with the other engaged institution. An Authorization/Reliance Agreement, per federal regulations at 45 CFR 46.114, allows UIndy to rely on another institution that has a valid, current FWA and an IRB on which the FWA relies. By relying on another IRB, UIndy satisfies compliance with its FWA.

If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, then they shall make a confidential report to the IRB Director/HPA, who will conduct a preliminary investigation. If circumstances warrant, then the IRB Director/HPA shall, in communication and cooperation with the IO and/or the IO’s delegate, conduct a thorough investigation and develop and implement a corrective and preventative action (CAPA) plan in order to prevent additional occurrences.
4.3 IRB RELATIONSHIPS

The IRB functions independently of, but in coordination with, other institutional regulatory or administrative committees. The IRB makes its independent determination whether to approve or disapprove a protocol on the basis of federal and institutional criteria for IRB approval. The IRB has review jurisdiction over all non-exempt human subjects research engaging UIndy.

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

The IRB Chair and/or Vice Chair and IRB Director/HPA shall meet with University officials on a regular basis.

4.3.1 RELATIONSHIPS WITH OTHER INSTITUTIONS

UIndy may choose, on a case-by-case basis, to provide human research protection oversight for another institution. In order for UIndy to provide this oversight, a formal relationship must be established between UIndy and the other institution through execution of an Authorization/Reliance Agreement (Agreement). This relationship must be formalized before UIndy will accept any human research proposals from the other institution.

In the conduct of cooperative research projects, UIndy acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. When UIndy investigators (i.e., agents) engage in human subjects research that engages (an)other institution(s), UIndy will invite other engaged institution(s) to execute an Agreement, whereby UIndy may rely on the other engaged institution’s IRB in order to comply with its FWA. When a valid Agreement exists, the UIndy may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. Execution of an Agreement is at the discretion of the IRB Director/HPA to whom the IO has delegated authority to review and execute Agreements. When executing an Agreement, the IRB Director/HPA will ensure that the review arrangement is thoroughly vetted and authorized by the appropriate officials of the institutions involved, and the particular characteristics of its local research context are considered, either (i) through knowledge of its local research context by the UIndy IRB or (ii) through subsequent review by appropriate designated institutional officials, such as the IRB Chair or Vice Chair and/or other IRB members.

When UIndy is the coordinating center for a multi-center protocol, the IRB will require the UIndy PI to ensure that IRB approval has been obtained at each participating site prior to initiation of the research at that site. At the time of initial review, the IRB will assess the procedures for dissemination of protocol information (e.g. unanticipated problems involving risks to participants or others, protocol modifications, interim findings) to all participating sites.
4.3.2 RELATIONSHIPS WITH INDIVIDUAL INVESTIGATORS

In instances when UIndy investigators intend to involve non-UIndy personnel as investigators in either a multi-site or multi-center study, UIndy must ensure that non-UIndy personnel satisfy all UIndy requirements for credentialing and validating investigators conducting human subjects research in compliance with UIndy’s FWA. In these instances, UIndy may elect to extend its FWA protections to non-UIndy personnel via an Individual Investigator Agreement (IIA). The IIA will extend UIndy’s FWA compliance protections to both (1) the independent investigator and (2) the institutional investigator:

(1) Independent investigator is
   (a) not otherwise an employee or agent of the assured institution;
   (b) conducting collaborative research activities outside the facilities of the assured institution; and
   (c) not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

(2) Institutional investigator is
   (a) not otherwise an employee or agent of the assured institution;
   (b) conducting collaborative research activities outside the facilities of the assured institution;
   (c) acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and
   (d) employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

When executing an AII, UIndy will abide by OHRP guidance found at http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html

4.4 ROLES AND RESPONSIBILITIES

4.4.1 INSTITUTIONAL OFFICIAL

The Executive Vice President and Provost serves as the Institutional Official (IO) for UIndy’s FWA. The IO acts on behalf of UIndy and assumes overall responsibility for compliance with the FWA. The IO has the legal authority to commit on behalf of UIndy and signs the FWA. The IO is responsible for appointing IRB members and Chair and supports IRB decisions. The IO has authority to further review research projects following IRB review and can approve or disapprove research projects, but cannot approve any research that has been disapproved by the IRB. The IRB Chair, Vice Chair and IRB Director/HPA report directly to the IO.

4.4.2 IRB CHAIR

The IO, in consultation and approval with the IRB members and the IRB Director/HPA, appoints an IRB member to serve in the role of IRB Chair. The term of service as Chair will coincide with the term of service as member. The IO may re-appointment the IRB Chair to consecutive terms.
not to exceed six consecutive years. Any change in appointment, including reappointment or removal, requires written notification.

In order to be eligible to serve as IRB Chair, the individual must have served for at least one year on the UIndy IRB or an IRB at another institution. Whenever possible, the IRB Chair will be a senior faculty member of UIndy.

The IRB Chair moderates IRB meetings and collaborates with the IRB Director/HPA in management of the IRB. The IRB Chair is a signatory for correspondence generated by the IRB.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions. The IRB Chair advises the IO and/or IO’s designee and IRB Director/HPA on IRB member performance and competence.

The IRB Chair acts on behalf of the IRB Committee and reports directly to the IO and/or IO’s designee.

4.4.3 Vice Chair

The Vice-Chair serves as substitute when the IRB Chair is unavailable. The Vice-Chair and IRB Chair may share responsibilities, thus serving as Co-Chairs. The Vice Chair serves as IRB Chair when the IRB reviews a research for which the IRB Chair serves as the Study PI.

4.4.4 Human Protections Administrator (HPA)

The Human Protections Administrator (HPA) serves as UIndy’s research ethicist and compliance officer for research subject to human research protections. The HPA manages the privileged and confidential institutional review approval process of all proposed research activities involving human subjects. The HPA receives all research protocols, communicates decisions to research investigators, and supporting documentation and forwards certification of IRB approval to appropriate research personnel. The HPA provides regular publications of meeting schedules and transmission of documents to and from investigators. The HPA ensures preparation and distribution of the agenda and review materials for IRB members prior to each meeting. The HPA ensures that minutes of IRB meetings are adequately recorded and maintained. The HPA maintains all records of IRB action for at least three years after the conclusion of the research. The HPA reviews and approves all exemption-eligible human subjects research. The HPA acts on behalf of the IRB and UIndy when collaborating/cooperating with other institutions on matters of human research protections. The HPA reports directly to the IO and/or IO’s designee.

4.4.5 Subcommittees of the IRB

The IRB Chair or IRB Director/HPA may designate one or more other IRB members (i.e., establish a sub-committee) to perform duties, as appropriate, for review, signature authority, and other IRB functions. When appropriate, individuals outside of the IRB membership may be included in subcommittees.
4.4.5.1 DUTIES OF A SUBCOMMITTEE

Duties of a subcommittee may include the following:

1. Serve as designees to the IRB Chair for the expedited review of new or continuing protocols, and/or modifications of continuing protocols. The subcommittee must be experienced in terms of seniority on the IRB, and must be matched as closely as possible with their field of expertise to the study.

2. Review and approve the revisions submitted by investigators for a protocol given conditional approval by vote of the full IRB.

3. Ensure fairness and expertise of an inquiry process. A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise of an inquiry process (See Section 11.3 for a discussion of the inquiry process). The subcommittee is given a charge by the IRB, which can include any or all of the following:
   a. Review of protocol(s) in question;
   b. Review of FDA audit report of the investigator, if appropriate;
   c. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects;
   d. Interview of appropriate personnel if necessary;
   e. Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting;
   f. Recommend actions if appropriate.

4. Conduct on-site review. Determination of the review interval 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 particularly risky research, 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.

5. Observe the consent process. When appropriate, the IRB may appoint a subcommittee to observe the consent process being used in a research project.

4.5 RESOURCES FOR IRB

The IO provides resources to the IRB and the IRB Director/HPA, 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 and staff will be reviewed during the annual budget review process.
4.6 CONDUCT OF QUALITY ASSURANCE/QUALITY IMPROVEMENT ACTIVITIES FOR IRB OPERATION

The IO and/or IO’s designee, through appropriate mechanisms, will monitor and review the processes and procedures of the IRB to ensure effectiveness, efficiency and compliance with both federal regulations and these policies and procedures.

The IRB Director/HPA will conduct investigations and audits of ongoing research when the IRB directs an audit be conducted or a complaint or allegation of non-compliance is received. In addition, the staff will conduct “not for cause” audits of research. (See Section 11 for a detailed discussion of investigations and audits.)
5.0 IRB MEMBERSHIP

5.1 COMPOSITION OF THE IRB

1. The UIndy will have at least five members with varying backgrounds to provide complete and adequate review of research proposals and issues related to approved research in process.

2. The IRB will be sufficiently qualified to complete its work. Membership appointments will be made with consideration for expertise, diversity, and sensitivity to community attitudes.

3. In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will have access to consultants to provide review assistance when specific areas of expertise are not available through appointed committee members.

4. If the IRB regularly reviews research that involves participants classified as vulnerable (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to appointing an IRB committee member with expertise in understanding the issues directly related to the specific vulnerable population.

5. Every effort will be made to ensure that the IRB does not consist entirely of men or entirely of women. No committee member appointments will be made on the basis of gender. IRB membership includes representation from disciplines on campus that actively submit research for review.

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

7. IRB membership includes at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with UIndy.

8. One member may satisfy more than one membership category.

9. The IRB Chair and Vice Chair will serve as a committee member with voice and vote.

10. The IRB Director/HPA will serve as a committee member with voice and vote.
5.2 APPOINTMENT OF MEMBERS TO THE IRB

The IRB Chair, Vice Chair and IRB Director/HPA will identify when a need exists for a new or replacement member or alternate member. They may nominate candidates and send the names of the nominees to the IO or IO’s designee. Deans, Department Chairs and others may also forward nominations for committee members to the IO or IO’s designee, the Human Protections Administrator, or the IRB Chair. The IO or IO’s designee will communicate with Deans, IRB Chair, Vice Chair and the IRB Director/HPA to ensure nominees represent the content expertise to conduct adequate review.

The IO or IO’s designee will communicate with nominees about their availability and willingness to accept appointment to the IRB. The IO or IO’s designee will confer with the IRB Chair, Vice Chair and IRB Director/HPA to ensure nominees satisfy appointment criteria and represent research interests. The IO or IO’s designee will authorize appointments and work with the HPA to document appointment (i.e., appointment letter).

IRB appointment has a term of service of three years. The term of service is renewable for an additional three years. After two consecutive terms, an IRB member is for one-year ineligible for additional service. A former IRB member may receive an offer for re-appointment after a minimum of one-year hiatus. Any change in appointment, including reappointment or removal, requires authorization from the IO or IO’s designee and formal documentation (e.g., letter). Members may resign by providing written notification to the Chair.

5.2.1 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 IRB roster identifies the primary member(s) for whom each alternate member may substitute. Alternates may attend any IRB meeting and are encouraged to attend as many meetings as possible. Although the alternate member will not be counted as a voting member unless the primary member is absent, they may freely participate in discussion. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB minutes will document when an alternate member replaces a primary member.

5.3 USE OF CONSULTANTS (OUTSIDE REVIEWERS)

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. Prior to committing to review, consultants will be informed of the University of Indianapolis conflict of interest policy. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the research or sponsor of the research will not be invited to provide consultation. Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a
manner that protects the researcher’s confidentiality and is in compliance with University of Indianapolis policies and procedures.

**5.4 CONFLICT OF INTEREST (COI) – IRB MEMBERS AND CONSULTANTS**

No IRB member or consultant will participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members and consultants are expected to self-identify conflicting interests. When a committee member or consultant identifies that a conflict of interest exists, the IRB Chair and/or Vice Chair and/or IRB Director/HPA will reassign the protocol.

Generally, a conflicting interest includes:
1. Participation in the project to be reviewed;
2. A financial interest (see below); and/or
3. Any other examples referenced below.

A conflict may arise because of an interest of the member or consultant or his/her family; the aggregate interest of the IRB member or consultant and family is considered.

“Participation in the project” generally means the member or consultant and/or family is listed on the protocol/project, or will be included as a co-author on a publication of the project’s results. This would include individuals or immediate family involved in the design, conduct, or reporting of the research. Participation in the project excludes a member of the IRB or consultant from reviewing and voting on the project under review.

The following financial interests may be considered a conflict of interest:

1. An ownership interest (equity or stock options) or other measures of fair market value to publicly traded prices in any one enterprise or entity in aggregate for the IRB member or consultant and his/her immediate family related to any project being reviewed.

2. Consulting fees, honoraria, speaking fees, travel expenses, stipends, dividends, salary, royalties, travel expenses, stock options, gifts or other payments for the IRB member or consultant and his/her immediate family from an external entity relating to any project being reviewed.

3. Compensation to the IRB member or consultant and his/her family of any amount that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

4. Proprietary or other financial interest by the IRB member or consultant and his/her family in the product to be used clinical trials including, but not limited to, a patent, trademark, copyright or licensing agreement.
Other examples of conflicting interests include but are not limited to:

1. Having certain non-financial interests that may raise a real or perceived conflict. These will depend on the circumstances. They may include, for example, having direct supervision over the investigator conducting the project. NOTE:

   a) a department director does not have a conflict simply by virtue of the position; a conflict could arise, though, if the director had a closer, direct supervisory relationship over a department researcher;

   b) if a junior person in an IRB member’s or consultant’s research group submits a protocol, the IRB member or consultant has a conflict and cannot review the protocol.

2. Any real or perceived conflict, or a concern that there may be a real or perceived conflict, that is not addressed above should be raised with either the IRB Chair, Vice Chair and/or the IRB Director/HPA. The IRB Chair, Vice Chair, and IRB Director/HPA have the authority to determine when COI exists as defined by institutional policy and to impose and enforce disciplinary action in the event that COI is not disclosed.

5.5 **DUTIES OF IRB MEMBERS**

IRB members have access to all materials and other study records through IRBManager. When a proposal requires full board review, all members will have access to the proposal in IRBManager at least one week before each meeting in order to participate fully in the review process. IRB members will treat the research proposals, protocols, and supporting data confidentially.

5.6 **ATTENDANCE REQUIREMENTS**

Members should attend all scheduled meetings. If a member is unable to attend a scheduled meeting, they should inform the IRB Chair or IRB Director/HPA. If the inability to attend will be prolonged, the committee member should submit a request for an alternate to the IRB Chair or IRB Director/HPA.

5.7 **TRAINING AND ORIENTATION/CONTINUING EDUCATION OF IRB MEMBERS AND LEADERSHIP**

A vital component of a comprehensive human research protection program is an education program for the IRB Chair Vice Chair, IRB Director/HPA, and committee members. UIndy is committed to providing training and an on-going educational process for IRB members related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.
5.7.1 **TRAINING AND ORIENTATION**

Initial training and orientation of ALL IRB members include:

1. Completion of CITI Certification in Human Research Protections

2. Completion of IRBManager Training

3. Meet with IRB Director/HPA to;
   a) Review of UIndy IRB website
   b) Review agendas and minutes from previous meetings
   c) Receive and review copy of “IRB Member Handbook”
   e) Review administrative processes of IRB review

4. Meet with IRB Chair for;
   a) Overview of meeting organization and conduct, and
   b) Overview of project review processes.

IRB Director/HPA must validate and document training and orientation of a prospective IRB member BEFORE that member conducts review.

5.7.2 **CONTINUING EDUCATION**

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Educational activities include, but are not limited to;

- In-service training at IRB meetings
- Training workshops
- Dissemination of current events articles relevant to human research protection
- Copies of “Institutional Review Board: Member Handbook”
- Maintaining CITI certification

The IO or IO’s designee will provide formal (e.g., advocacy) and material (e.g., funding) support for the IRB Director/HPA and IRB members to attend local, regional and national conferences that promote professional development in human research protections.

The IRB Director/HPA must earn and sustain the Certified IRB Professional (CIP) credential.

5.8 **LIABILITY COVERAGE FOR IRB MEMBERS**

UIndy will indemnify and defend UIndy faculty and staff performing within the course and scope of their employment (e.g., IRB responsibilities). This coverage extends to those under the
supervision of faculty and staff (e.g., students and staff), and volunteers (i.e., unaffiliated IRB members).

5.9 REVIEW OF IRB MEMBER PERFORMANCE

The IRB Member’s performance will be reviewed on an annual basis by the IRB Director/HPA in consultation with the IRB Chair and Vice Chair. Members who are not acting in accordance with the IRB’s mission or policies and procedures or who have an undue number of absences will be replaced.
6.0 IRB Records

The IRB prepares and maintains adequate documentation of committee activities. Documents prepared and maintained by the IRB include (but are not limited to) research proposals, recruitment materials, scientific evaluations (if any) that accompany the proposals, approved consent documents, approved HIPAA Authorization documents (if separate from the informed consent) proposed protocol amendments and the IRB action on each amendment, progress reports, reports of injuries to subjects, reports of serious and unexpected adverse events, documentation of protocol violations, and documentation of non-compliance with applicable regulations.

The IRB records must also include documentation of continuing review activities and copies of all correspondence between the IRB and investigators. Statements of significant new findings provided to subjects must be maintained with the related research proposal and, when reviewed at an IRB meeting, must be documented in the minutes.

6.1 Minutes of an IRB Meeting

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:

1. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area;

2. Alternate members attending the meeting and, if voting, for whom they are substituting;

3. Actions taken by the IRB, including those involving full review. The IRB must use the minutes to notify IRB members of actions taken through expedited review and those studies that have been determined to be exempt from IRB review;

4. Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB;

5. Documentation that the research meets the four required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent;

6. Documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived;
7. When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB’s justifications and findings regarding the determinations stated in the Subparts or the Committee’s agreement with the findings and justifications as presented by the investigator on IRB forms;

8. The vote on actions, including the number of members voting for, against, and abstaining;

9. A note indicating that when an IRB member has a real or potential conflict of interest relative to the proposal under consideration, that the IRB member was not present during the deliberations or voting on the proposal (and that the quorum was maintained);

10. The basis for requiring changes in or disapproving research and documentation of resolution of these issues when resolution occurs;

11. A written summary of the discussion of protocol related challenged issues and their resolution;

12. Review of additional safeguards required as a condition of IRB approval to protect vulnerable populations (if entered as study subjects) when this is not otherwise documented in IRB records;

13. The determination of the level of risk, if not recorded elsewhere in IRB records;

14. The frequency of continuing review of each proposal, as determined by the IRB, if not recorded elsewhere in IRB records;

15. Documentation, as required by 45 CFR 164(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization.

6.2 MEMBERSHIP ROSTERS

A list of IRB members must be maintained. The list must contain the following information: member’s name, earned degrees, affiliated or non-affiliated UIndy status, status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist); voting status, alternate status, or status as chairperson. This list should also describe each member's chief anticipated contributions to IRB deliberations. A current Curriculum Vitae (CV) for the IRB member must also be maintained by the IRB.

The UIndy IRB Director/HPA must keep the IRB membership list current. The UIndy IRB Director/HPA must promptly report changes in IRB membership to UIndy administration and OHRP via update of the IRB registration.
6.3 RECORDS RETENTION REQUIREMENTS

The above detailed records must be stored securely in the office of the IRB Director/HPA and must be retained for at least 3 years after the completion of the research. All records must be accessible for inspection and copying by authorized representatives of the federal OHRP and other authorized entities at reasonable times and in a reasonable manner.

Electronic records are maintained in IRBManager™. Hard copy (e.g., paper, CDs, etc.) materials are maintained in locked file cabinets in the locked office of the IRB Director/HPA. Access to these files is generally limited to IRB members (including the Chair) and the IO (who serves as the IRB Institutional Official). File access logs are maintained to record the following information: files accessed (when other than an IRB member or designated Institutional Official), specific files accessed; date of access; and purpose of access.

6.4 WRITTEN PROCEDURES AND GUIDELINES

The UIndy Policies and Procedures for Human Research Protection Manual (i.e., Manual) details the policies and procedures governing research with human subjects in compliance with federal, local and institutional regulations, laws and ethical standards.

Policies and Procedures include:

1. Written procedures that the IRB follows for the following activities:
   a. Conducting initial and continuing reviews of research and for reporting review findings and actions to the investigator and the University;
   b. Determining which projects require review more often than annually;
   c. Determining which projects need verification that no material changes have occurred since previous IRB review from sources other than the investigators;
   d. Ensuring prompt reporting of proposed changes in a research activity to the IRB;
   e. Ensuring that changes in an approved research protocol, (during the period for which IRB approval has already been given) may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

2. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Federal Department or Agency head of any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB suspension or termination of IRB approval.
7.0 IRB REVIEW PROCESS

These procedures and guidelines apply to all human subjects research engaging UIndy, regardless of sponsorship and performance site.

7.1 HUMAN SUBJECTS RESEARCH DETERMINATION

The responsibility for determining initially whether an activity constitutes human subjects research rests with the investigator. Because UIndy holds investigators responsible for incorrect determinations, investigators must consult with the IRB Director/HPA in order to make initial determination of human subjects research. UIndy classifies research into four categories vis-à-vis federal regulations for human research protections review:

1. Not Human Subjects Research; A project does NOT satisfy the federal regulatory definition of “research” OR “human subjects research” as set forth above in Section 2.0 and is not eligible for human research protections review.

2. Research Subject to Human Research Protections and Review
   a) Exemption Eligible; A project satisfies the definitional criteria of “human subjects research” AND satisfies eligibility criteria for one or more of the federal regulatory exemption categories as set forth above in Section 3.4.
   b) Non-exempt Human Subjects Research
      (i) Expedited review (Section 7.7)
      (ii) Full board review

7.2 EXEMPT RESEARCH

Per current policy, UIndy delegates to the IRB Director/HPA review and approval of exemption-eligible human subjects research. See Section 3.4 above for details.

7.3 FULL BOARD REVIEW PROCEDURES

Except when an expedited review procedure is used (See Section 7.7), the IRB must review proposed research at convened meetings (also known as Full-Board meetings) at which a quorum (see below) is present.

7.3.1 SCHEDULE OF IRB MEETINGS

The IRB meets typically on the first Tuesday of the month, except for January, June, July and August. The IRB will as needed schedule meetings during the summer months. The schedule for the IRB may vary due to holidays or lack of quorum. The schedule of meetings for the IRB will
be posted on the IRB website and will also be listed on the University of Indianapolis Committee Calendar.

### 7.3.2 Conduct of Meetings

The IRB shall conduct its meetings according to the most recent version of *Robert’s Rules of Order*.

### 7.3.3 Quorum

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. The IRB Chair or Vice Chair, in consultation with the IRB Director/HPA, if present, will confirm that an appropriate quorum is present before calling the meeting to order.

A quorum must be present for each vote involving matters of human research protections review. The meeting minutes must document any change of quorum status (e.g., a member leaves) and quorum status at the time of a vote. In the event the IRB loses and cannot reestablish quorum and the IRB has scheduled votes yet to complete, the IRB will postpone remaining business and adjourn the meeting.

All roster members present at a convened meeting have full voice and vote, except in the case of a conflict of interest (see Section 5.4 above). Research protocols must receive the approval of a simple majority of the voting members present at the meeting.

IRB members should be physically present at convened meetings. If physical presence is not possible, then a member may participate virtually (e.g., Skype, telephone, etc.). In this case, the member must have had access and reviewed in IRB Manager all pertinent material prior to the meeting, and must be able to participate actively and equally in all discussions.

Members who plan to be absent may submit questions/comments for consideration during IRB deliberation to the IRB Chair, Vice Chair, or IRB Director/HPA. Members may NOT vote *in absentia*.

### 7.3.4 Full Board Initial Review Procedures

#### 7.3.4.1 Submission Materials through IRB Manager

Investigators must submit via IRB Manager™ all proposals for research subject to human research protections review (i.e., exempt eligible and non-exempt research). **Note:** Study PIs who have other individuals (e.g., student co-investigator) write their applications and responses to the IRB must recognize that the ultimate responsibility of any study lies with the Study PI. Therefore, UIndy requires the Study PI to monitor and authorize all materials and information submitted to the IRB for review.
7.3.4.2 ADMINISTRATIVE PREVIEW

The IRB Director/HPA conducts Administrative Preview in order to confirm IRB review eligibility, and identify errors and/or omissions requiring rectification in preparation for IRB review. The IRB Director/HPA will share Administrative Preview findings with investigators, and collaborate with investigators to address findings prior to forwarding complete application for human research protections review. NOTE: Administrative Preview does NOT constitute or substitute for IRB review.

7.3.4.3 DESIGNATED PRIMARY REVIEWERS

The IRB Director/HPA, in consultation with the IRB Chair or Vice Chair, designates two IRB members as primary reviewers of a proposal satisfy criteria for full board review. The IRB Director/HPA and IRB Chair/Vice Chair designate reviewers on the basis of reviewers’ related expertise and experience with study specific population(s). The responsibilities of the designate primary reviewers are:

1. Prior to full board meeting, review per federal, state and institutional criteria for IRB approval all submitted proposal materials and information;

2. Identify deficiencies and require remedies prior, so that revised version of proposal satisfies approval criteria;

3. Report findings to full board during meeting. At the meeting, primary reviewers present an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. Particular attention is paid to the risk/benefit ratio of the investigation and the adequacy of the consent form in conveying human subject issues and concerns.


7.3.4.4 PRE-MEETING REVIEW BY IRB MEMBERS

IRB members will receive notification of full board activities no less than one week prior to scheduled IRB meeting. The notification will include a meeting agenda with information about full board activities requiring review prior to the meeting. IRB members will access all meeting materials and proposal applications through IRBManager™.

7.3.4.5 CONSULTANTS

When necessary, the IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. The consultant’s findings will be presented to the full board for consideration either in person or by the IRB Director/HPA. If in attendance, these individuals will provide consultation but will not participate in or observe the vote. Prior to committing to provide assistance to the IRB, consultants will be informed of the IRB regulations regarding conflict of interest. Individuals
who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation. Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher’s confidentiality and is in compliance with the IRB conflict of interest policy.

**7.3.4.7 ADDITIONAL CONSIDERATIONS**

**7.3.4.7.1 DETERMINATION OF RISK**

At the time of initial and continuing review, the IRB will make a determination of the overall risk profile of the research protocol. The IRB will identify and evaluate the nature, probability and severity of risks vis-à-vis the design of the study to minimize known and foreseeable risks. The IRB will classify the research as either “at or less than minimal risk” or “greater than minimal risk” based on the IRB’s assessment and interpretation of “minimal risk” as defined in the federal regulations. The meeting minutes will reflect the IRB’s determination of overall risk profile.

**7.3.4.7.2 PERIOD OF APPROVAL/FREQUENCY OF REVIEW**

At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocols (i.e., the length of the approval period). All protocols will be reviewed by the IRB at intervals appropriate to the risk profile, but no less than once per year. Depending on the circumstances of a particular study, the IRB may approve a shorter and/or conditioned approval period (e.g., semi-annually, after accrual of a specific number of participants, etc.). The meeting minutes will reflect the IRB’s determination regarding review frequency.

The following factors will determine which studies require review more frequently than on an annual basis:

1. Probability and magnitude of anticipated risks to subjects
2. Likely medical condition of the proposed subjects
3. Overall qualifications of the principal investigator and members of the research team
4. Specific experience of the principal investigator and other members of the research team in conducting similar research
5. The nature and frequency of adverse events observed in similar research at this and other institutions
6. The novelty of the research making unanticipated adverse events more likely
7. Other factors that the IRB deems relevant.
NOTE: IRB will NOT authorize an approval period of more than one year for studies that are greater than minimal risk!

7.3.4.7.3 INDEPENDENT VERIFICATION REGARDING MATERIAL CHANGES

Protecting the rights and welfare of subjects sometimes requires that the IRB independently verify study related information, utilizing sources other than the investigator. Types of information that may necessitate independent verification by the IRB includes (but is not limited to) adverse event reporting, data in the scientific literature, reports of drug toxicity, drug or device approval status, and adherence to the procedures described in the approved protocol.

The IRB will consider the following factors in determining which studies require such independent verification:

1. The probability and magnitude of anticipated risks to subjects
2. The likely condition of the proposed subjects
3. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed
4. Prior experience with the principle investigator and members of the research team
5. Any other factors that the IRB deems relevant.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, may retrospectively require such verification at the time of continuing review, or may require such verification at any time during the approval period in the light of new information.

7.3.4.7.4 CONSENT MONITORING

In reviewing the adequacy of informed consent procedures for proposed research, the University of Indianapolis IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence.

Such monitoring may be particularly warranted when the research presents significant risks to subjects or if subjects are likely to have difficulty understanding the information to be provided. Monitoring may also be appropriate as a corrective action when the IRB has previously identified problems associated with a particular investigator or a research project.
7.3.4.7.5 **CATEGORIES OF RESEARCH INVOLVING CHILDREN**

During review and deliberation of research involving children as the target population, the IRB will determine and document in the minutes the appropriate category as set forth in the federal regulations at 45 CFR 46 Subpart D:

Category I: Research not involving greater than minimal risk.

Category II: Research involving greater than minimal risk with prospect of direct benefit to participant.

Category III: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Category IV: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

On the basis of category determination, the IRB will also determine requirements/alterations for informed consent/assent/parental permission procedures.

7.3.4.7.6 **MEETING PROCEDURES**

1. Attendance and determination of quorum (Section 7.3.2)

2. Declaration of Conflicts of Interest (Section 5.4)

3. Review of proposal

   a) Introduction of and presentation by Study PI (optional)

      (i) IRB Director/HPA and/or IRB Chair/Vice Chair invite Study PI to attend and give overview of study proposal;

      (ii) Study PI give overview and addresses questions/concerns from IRB members

      (iii) IRB Chair/Vice Chair excuse Study PI after presentation

   b) Designated primary reviewers present an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. Particular attention is paid to the risk/benefit ratio of the investigation and the adequacy of the consent form in conveying human subject issues and concerns.

   c) Introduction of consultant and/or findings
4. Motion

5. Discussion, including controverted issues, revision requirements to satisfy approval criteria

6. Vote

**7.3.4.7.7 MOTIONS/ACTIONS TAKEN BY VOTE**

**Approval:** The study is approved as submitted.

**Conditional Approval (Approvable Pending Revisions to Satisfy Approval Criteria):** The proposal and/or consent form require minor revisions, such as wording changes, with replacement language provided. The needed revisions are agreed upon at the meeting. These revisions are presented to the Principal Investigator for incorporation by simple concurrence. The IRB Chair or Vice Chair and the IRB Director/HPA may approve the study upon receipt and approval of the revisions without further action by the full IRB.

**NOTE:** Approval of the proposal application will not be granted and certification will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB. The date of approval is the date the minor changes were approved by the IRB Chair or Vice Chair AND the IRB Director/HPA.

**Deferred for substantive issues:** The proposal and/or consent form require major substantive revisions that must be addressed to the satisfaction of the IRB. This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the proposal application adequately (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed research cannot occur until committee members review the revised and complete protocol at a subsequent meeting of the convened IRB.

If review of the proposal is deferred the following will occur:

1. The decision to defer the review of the protocol is documented in the IRB meeting minutes;

2. The University of Indianapolis IRB Office informs the investigator in writing of the IRB's decision, questions and concerns;

3. The investigator's response is sent to the University of Indianapolis IRB Office. The IRB Office distributes to the IRB members the investigator’s response, the updated and revised protocol and a copy of the previously submitted protocol. The item is placed on the agenda for the following meeting;

4. The protocol application is reviewed at a convened meeting of the IRB;
5. The outcome of the IRB's deliberations is communicated to the investigator in writing;

6. The IRB's determination is documented in the IRB meeting minutes.

**Not Approved:** The IRB may take this action when it finds that the risks to which the proposal exposes participants cannot be justified vis-à-vis potential benefits of participation and/or the risks cannot be minimized with further revisions. When the IRB motions and votes to approve this action, the IRB will NOT review the study again.

**Approval in Principle** [45 CFR 46.118]
There are two circumstances in which the IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents. One is if study procedures are to be developed during the course of the research, but human subjects’ approval is required by the sponsoring agency. The other is if the involvement of human subjects depends on the outcomes of work with animal subjects. The IRB may then grant approval without having reviewed the as yet undeveloped recruitment, consent, and intervention materials. If the proposal is funded, the Principal Investigator must submit such materials for approval at least 60 days before recruiting human subjects into the study, or into any pilot studies or pre-tests. Approval in principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects.

**7.3.5 REPORTING IRB ACTIONS**

All IRB actions are communicated to the Study Principal Investigator (PI), or designated primary contact person for the protocol, in writing within ten (10) working days by the IRB Director/HPA. The IRB will provide the Study PI with written notification regarding IRB decisions to approve or disapprove the proposed research activity or written details regarding any modifications required to secure IRB approval of the research activity.

For approved research, investigators are informed that:

1. **Subsequent modifications to the approved research protocol** must be reviewed and approved by the IRB before they are initiated;

2. **Unexpected adverse events/reactions** must be reported to the IRB within ten working days of receipt;

3. **The IRB may monitor research activities.** The type and frequency of monitoring will be determined by the IRB at the time of initial or continuing review. The IRB will inform the principal investigator of monitoring requirements in writing.

If the IRB decides to disapprove or require modifications to secure approval of a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
The IRB reports its findings and actions to the institution in the form of its minutes, which are available upon request by University of Indianapolis institutional officials. Minutes are stored permanently and securely in IRBManager™.

7.4 CONTINUING REVIEW OF ACTIVE PROTOCOLS

Approved research is subject to continuing IRB review at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)], but not sooner than 30 days prior to the protocol termination (expiration) date. This review must take place before the approval expiration date; any lapse in approval will result in suspension of subject recruitment, enrollment, data collection, and, if the research is DHHS-sponsored, notification of the funding Agency. The approval date and the termination (expiration) date are clearly noted on all IRB communications sent to the PI and must be strictly adhered to. Investigators should include in their project planning sufficient time for development and review of renewal submissions.

The Human Protections Administrator will send the principal investigator (or designated contact persons) project renewal notices at intervals of two months and one month in advance of the expiration date. It is the investigator’s responsibility to ensure that the continuing review approval is secured prior to the expiration date. Information regarding submission guidelines for continuing review is available from the University of Indianapolis IRB website and from the University of Indianapolis Protocol Submission Document Guidebook. Following continuing review approval, the IRB will make a determination regarding the frequency of subsequent review(s). As previously noted, protocols will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year. By federal regulation, no extension to the project expiration date can be granted.

Research activities are subject to internal audit and verification from sources other than the investigator that no material changes have occurred since the last IRB review.

7.4.1 CONTINUING REVIEW PROCESS

In accordance with Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and at 46.115(a)(2), continuing review by the convened IRB, with recorded vote on each study, is required unless the research is otherwise appropriate for expedited review under Section 46.110 (see below). Furthermore, DHHS regulations set forth the criteria that must be satisfied in order for the IRB to approve research (45 CFR 46.111). These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review. The procedures for continuing review by the convened IRB may include a primary reviewer system.

In conducting continuing review of research protocols which are not eligible for expedited review, all IRB members should minimally receive and review a protocol summary (i.e., Description of Study) and a status report on the progress of the research. Status reports should include the following information from the past year (cumulative data must also be included after the first renewal):
• the number of subjects enrolled;
• number of subjects who withdrew prematurely and reason(s) for their withdrawal;
• a current copy of the Description of Study;
• a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
• summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
• any relevant multi-center trial reports;
• any other relevant information, especially information about risks associated with the research;
• a copy of the current informed consent document which has been signed by one research participant;
• any newly proposed additions or changes to the consent document;
• the current HIPAA Authorization document.

At least one member of the IRB will receive a copy of the complete protocol, including any modifications previously approved by the IRB. Furthermore, upon request, any IRB member has access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

When reviewing the current informed consent document(s), the IRB will ensure the following:

• The currently approved or proposed consent document is still accurate and complete;
• Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.116(b)(5).

Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

**7.4.2 Expedited Review of Continuing Review**

Generally, research that does not qualify for expedited review at the time of initial review does not qualify for expedited review at the time of continuing review. In some circumstances a protocol initially reviewed using full review procedures may have changed or will change. If these changes result in the protocol meeting the criteria for expedited review described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see Expedited Review Categories), the IRB may choose to complete the continuing review process using expedited procedures. It is also possible that research activities that previously qualified for expedited review in accordance with 45 CFR 46.110, have changed or will change. If these changes result in the protocol meeting the criteria for full review or if the IRB determines that the level of risk warrants, the IRB must complete the continuing review process using full review procedures.
7.4.3 **How is the Continuing Review Date Determined**

Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and 109(e) require, respectively, that:

(1) except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas; and

(2) an IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects.

At the University of Indianapolis, the protocol review interval and need for additional IRB supervision and oversight is determined on a protocol-by-protocol basis. For example, the IRB may elect to closely monitor the activities of an investigator who recently had a protocol suspended by the IRB because of regulatory concerns. The IRB may also elect to closely monitor research activities associated with particularly risky research protocol. Monitoring activities may include (but are not limited to) on-site reviews by a subcommittee of the IRB or scheduled audits of study performance at specified intervals (after a few months of enrollment, after enrollment of the first several subjects).

The date by which continuing review must occur depends on the date of the convened meeting at which IRB approval occurs. For protocols reviewed by the IRB at a convened meeting, several scenarios for determining the date of continuing review apply. These examples presume the IRB has determined that the project will expire in one year.

**Scenario 1:** The IRB reviews and approves a protocol without any conditions at a convened meeting on October 1, 2006. Continuing review must occur within 1 year of the date of the meeting, that is, by October 1, 2007.

**Scenario 2:** The IRB reviews a protocol at a convened meeting on October 1, 2006 and approves the protocol contingent on specific minor conditions that will be verified by the IRB chair. On October 31, 2006, the IRB chair confirms that the required minor changes were made. In this instance, the continuing review must occur within 1 year of the date of the convened IRB meeting at which the IRB reviewed and approved the protocol, that is, by October 1, 2007.

**Scenario 3:** The IRB begins their review of a research protocol at a convened meeting on October 1, 2006. Because of serious concerns about the protocol, the deliberation continues during the October 15 and October 29, 2002 meetings. At the October 29, 2006 meeting, the IRB completes the full review process and approves the study. Continuing review must occur within 1 year of the date of the convened meeting at which the IRB reviewed and approved the protocol, that is, by October 29, 2007.
For a study approved under expedited review, continuing review must occur within 1 year of the date the Expedited Reviewer gives final approval to the protocol.

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 it.

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 on or before the date when IRB approval expires. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. This would be, for example, October 1, 2007, in the above Scenarios 1 and 2, and October 29, 2007, in Scenario 3, even if the continuing reviews took place up to 30 days prior to these dates.

7.4.4 WHAT OCCURS IF THERE IS A LAPSE IN CONTINUING REVIEW

The IRB and investigators must plan ahead to meet required continuing review dates. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

As a courtesy, the University of Indianapolis IRB Office will send out renewal notices 60 and 30 days before a research protocol expires. However, it is ultimately the investigator's responsibility to initiate a renewal application (allowing sufficient time for the review and re-approval process to be completed) before the current approval expires. Retrospective approval for work done after the expiration date cannot be granted.

The continuation of research after expiration of IRB approval is a violation of the Federal Regulations. If the IRB has not reviewed and approved a research study by the study's current expiration date (IRB approval has expired), all research activities should stop. No new subjects may be enrolled in the study.

7.4.5 STUDIES THAT ARE APPROVED BUT NEVER STARTED

Written progress reports should be received from the investigator for all IRB approved protocols prior to the date of expiration. If a protocol is cancelled prior to participant enrollment, the principal investigator must submit a project closure report to the IRB. The IRB will maintain the protocol records for at least three years after cancellation.
7.5 MODIFICATIONS OF AN APPROVED PROTOCOL

Investigators must obtain IRB approval before making any changes to an approved protocol. The only exception to obtaining prior approval would be when changes are needed to eliminate an immediate hazard to research participants. If the principal investigator must make a protocol change to eliminate a hazard to the research participant, the IRB must be notified promptly following the change. The IRB will review the change to determine that it is consistent with ensuring the subjects' continued welfare.

Modifications may be approved if they are within the scope of the initial IRB authorization. For example, if a researcher proposes to add a population to an existing study, but not alter the study procedures or purpose, a modification request is usually appropriate. Likewise, modifying a procedure without changing the study's purpose or study population may also be appropriate. If changes are substantial (the researcher proposes to add a population and revise study procedures), the principal investigator must submit a new application for human subjects’ approval. The Application for Revision to a Previously Approved Protocol form should be used by investigators who wish to request approval of amendments or minor modifications. If the initially approved study will not be conducted, a Project Closure form should be submitted.

The IRB may use expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized [45 CFR 46.110; 63 FR 60364-60367, November 9, 1998]. An expedited review may be conducted by the IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB.

7.5.1 PROPOSED CHANGES IN A RESEARCH STUDY THAT ARE NOT MINOR

Changes that are NOT considered by the IRB to be minor include multiple modifications to an existing protocol, the addition of research procedures that increase participant risk, and/or the addition of participation procedures that add or increase participant discomfort. The IRB must review and approve the proposed change(s) at a convened meeting before the revised protocol can be implemented. The only exception to this policy is described in section 7.5.

7.6 ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Adverse events and data safety monitoring reports received by the University of Indianapolis IRB Office are reviewed by the IRB Chair to determine the relationship between the event and subject participation in the research protocol. Adverse events evaluated as not directly related to study participation and/or not related to an increased level of participant risk can be reviewed using expedited procedures. All other Adverse Events reports are reviewed by the IRB at the next convened meeting.

All reports of unanticipated problems are initially reviewed by the Human Protections Administrator. After reviewing the report, the HPA may contact the investigator for discussion or request further information about the problem. After determining the nature and scope of the problem, one or more of the following actions will be initiated:
1. If the unanticipated problem is serious, the HPA will forward the report to the IRB Chair for review and immediate response.
2. If the unanticipated problem is not serious, the HPA will file the unanticipated problem report in the IRB protocol record.
3. The seriousness of the problem may result in the need to revise the consent document(s) or protocol.

7.7 **EXPEDITED REVIEW OF RESEARCH**

According to 45 CFR 46.110, the IRB may use expedited procedures to review research appearing on the list AND found by the reviewer(s) to involve:

- no more than minimal risk and/or
- minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

An internet search for 45 CFR 46.110 will direct you to the section of the US Department of Health and Human Services Code of Federal Regulations document titled “Categories of Research That May Be Reviewed through an Expedited Review Procedure.”

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology; (iii) the number of subjects enrolled in the research (no greater than 10% of the total requested); (iv) the qualifications of the research team; (v) the facilities available to support safe conduct of the research; or (vi) any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

When a protocol is reviewed using expedited procedures, the review is completed by the IRB Chair or Human Protections Administrator and one or more members of the IRB committee designated by the Chair or Human Protections Administrator. IRB committee members are selected to participate in the expedited review process based on their familiarity with the review criteria and subject area expertise. Alternate members will not be designated as expedited reviewers.

All IRB members participating in the expedited review process receive and review the complete protocol. Documentation that would normally be submitted for a full-board review is reviewed by the IRB.

Using expedited review procedures, the reviewers exercise all of the authorities of the IRB. The only exception is that research may not be disapproved by the IRB using expedited review procedures. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 45 CFR 46.108.
7.7.1 Categories of Research Eligible for Expedited Review

The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. 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. The categories in this list 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.
- The expedited review procedure may not be used for classified research involving human subjects.

Research Categories one (1) through seven (7) are eligible for initial and continuing IRB review using expedited procedures.

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. (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.)
   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.

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 children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the
frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

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. uncannulated saliva collected either in an unstimulated 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 subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques

i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

j. sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples include:

a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy

b. weighing or testing sensory acuity
c. magnetic resonance imaging

d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography

e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (as described in Section 4.2.3 below). This listing refers only to research that is not exempt.

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (as described in Section 4.2.3 below). This listing refers only to research that is not exempt.

8. Continuing review of research previously approved by the convened IRB where:

   a. the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or

   b. no subjects have been enrolled and no additional risks have been identified; or

   c. the remaining research activities are limited to data analysis.

   [Of note, category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.

   For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), 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.]

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the 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 convened IRB.

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

7.8 FURTHER REVIEW/APPROVAL OF IRB ACTIONS BY OTHER WITHIN THE UNIVERSITY

Research that has been approved by the IRB is subject to review and disapproval by institutional officials, but those officials may not approve research that has been disapproved by the IRB. [45 CFR 46.112]

7.9 INITIATION OF RESEARCH PROJECTS

All research involving human subjects must be reviewed and approved by the IRB prior to initiation of the research project. Approved research is subject to continuing review by the IRB at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)]. The date of continuing review will be based on the date of IRB approval. [refer to the section on Continuing Review for further details.]

The approval date and the expiration date are clearly noted on all IRB certifications sent to the PI. Please allow sufficient time for development and review of renewal submissions. By federal regulation, no extension to the expiration date can be granted.

If a protocol has expired, it must be resubmitted for IRB review.

Research activities are subject to internal audit and verification from sources other than the investigator that no material changes have occurred since the last IRB review.
The IRB reserve the right to observe the consent process conducted under any research protocol and to inspect the records of investigators to ensure the protection of the human research subjects.

7.10 APPEAL OF IRB DECISIONS

If a subcommittee of an IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by the convened appropriate IRB.

If the convened IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator should first discuss the matter with the IRB Chair or the Human Protections Administrator, taking care to explain the reasons for believing that the proposed procedures are in compliance with University policy and with Federal regulations. If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision of the IRB, in writing. The IRB will reconsider the appeal based upon the new information provided and will continue to re-review protocols as long as the investigator wishes to appeal.
8.0 CRITERIA FOR IRB APPROVAL OF RESEARCH

The IRB must determine that all of the following requirements are satisfied in order to approve research (45 CFR 46.111).

1. Risks to research participants are minimized by using procedures which (i) are consistent with sound research design; (ii) do not unnecessarily expose subjects to risk; and (iii) whenever appropriate, are already being performed for diagnostic or treatment purposes.

2. Risks to research participants are reasonable in relation to (i) anticipated participant benefits (if any) and (ii) 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 persons 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 research participants 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. The IRB should be particularly aware of any special problems that may be attributed to research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be obtained from each prospective research participant or the research participant's legally authorized representative, in accordance with, and to the extent required by §46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

6. The research plan makes adequate provisions for safeguarding and monitoring the collected data to protect the safety of the research participants.

7. The research plan makes adequate provisions for protecting the privacy of research participants and maintaining the confidentiality of personal data.

8. The research plan includes additional safeguards to protect the rights and welfare of participants who are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).
8.1 Risk/Benefit Assessment

The goal of the risk/benefit assessment is to ensure that the risks posed by participation in the research are justified by the anticipated benefits to the subjects or society. Toward that end, the IRB must:

1. judge whether the anticipated benefit (new knowledge or improved health and welfare of the research subject) justifies asking any person to undertake the risks; and/or
2. disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

Assessing the risks and benefits of proposed research is one of the major responsibilities of the IRB. The assessment of research related risk involves a series of six steps which include:

1. identify the risks associated with the research (as distinguished from the risks of therapies the subjects would receive even if not participating in research);
2. determine whether the risks will be minimized to the extent possible;
3. identify probable benefits to be derived from the research;
4. determine whether the risks are reasonable in relation to the benefits to research participants (if any),
5. assess the importance of the knowledge to be gained;
6. ensure that potential research participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.

It is the responsibility of the investigator to minimize any research-related risks that may reasonably cause harm to participants. To this end, investigators must

1. use procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
2. use procedures already being performed on the subjects for diagnostic or treatment purposes (whenever appropriate).

For research to be approved the IRB must determine that (i) the risks associated with research participants are reasonable in relation to anticipated benefits (if any) and (ii) the importance of the knowledge that may reasonably be expected to result is greater than the risk incurred.

1. 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.
2. The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

### 8.1.1 Scientific Merit

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

1. The investigator(s) will be using procedures consistent with sound research design;

2. The research design is sound enough to reasonably expect that the investigators will be able to answer their proposed question(s); and

3. The knowledge expected to result from this research is sufficiently important to justify the risk.

In making this determination, the IRB may draw on its own knowledge and disciplinary expertise, or the IRB may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency, or departmental review. Departmental scientific review is documented by the signature of the administrative official responsible for the investigator’s research unit on new protocol applications.

### 8.2 Selection of Subjects is Equitable

The IRB assesses the inclusion/exclusion criteria to determine if the selection of research participants is equitable. In making this assessment, the IRB takes into account the purposes of the research and the setting in which the research will be conducted. The IRB will specifically take into account any special problems that may develop when research involves vulnerable populations (such as children, prisoners, fetuses, pregnant women, human in vitro fertilization, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged).

### 8.2.1 Recruitment of Research Participants

The IRB will review all recruitment procedures, materials and advertisements. The purpose of this review is to ensure that the recruitment process (including scripts, advertisements and postings) is (i) consistent with the procedures described in the protocol, (ii) presents a clear and accurate overview of the research purpose and related activities, and (iii) is non-coercive. When the research proposal includes research participant compensation, the IRB will review the amount (or type) of payment and the proposed method and timing of disbursement. The purpose of this review is to assure that the proposed compensation (or the timing of compensation) is not coercive (does not present an undue influence). Payment to participants should not be identified as a research participant benefit during the recruitment process, in the Letter of Informed Consent, or on any research study related materials.
8.3 **INFORMED CONSENT**

Informed consent will be obtained from each prospective research participant or the participant’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. In addition, the IRB ensures that the procedures described in the protocol for documentation of informed consent are in accordance with, and to the extent required by 45 CFR 46.117 (see Section 9 below for detailed policies on informed consent).

8.4 **DATA SAFETY MONITORING PLAN**

The IRB will review the data safety monitoring plan for protocols involving more than minimal risk during initial review and at continuing review.

8.5 **PRIVACY AND CONFIDENTIALITY**

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

8.5.1 **REGULATIONS**

According to 46.102(f), a human participant is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or **identifiable private information**.

- **Private information** is defined as 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 defined as information where the identity of the individual is or may readily be ascertained by the investigator or associated with the information.

8.5.2 **CONFIDENTIALITY**

Confidentiality and anonymity are different concepts. When data is anonymous, no one (not just members of the research team) can identify specific individuals or the data they provide. It is important to remember that names are not the only identifiers. In certain circumstances, participants can be identified based on other pieces of demographic information. Confidentiality means that information either about or from research participants will not be improperly divulged by any member of the research team. Information regarding certificates of confidentiality is found in section 14.1.

8.6 **VULNERABLE POPULATIONS**

It is the responsibility of the IRB to determine if appropriate safeguards are in place to protect the rights and welfare of research participants. When research participants are likely to be
members of a vulnerable population, additional safeguards may be warranted. Policies regarding vulnerable populations are found in section 10.
9.0 INFORMED CONSENT

9.1 INFORMED CONSENT PROCESS

No investigator may involve a human being as a research participant without obtaining legally effective informed consent. In most cases, informed consent will be obtained directly from the research participant or the participant’s legally authorized representative. In certain circumstances, an investigator may request that the IRB approve a waiver of consent (see Section 9.3 of this policy).

Individuals must exhibit mental competence as a prerequisite to providing informed consent. Persons who lack sufficient competence to sign legal documents or consent for medical care may also lack the decision making capacity necessary for providing informed consent to participating in research. A variety of assessments and tools (such as the Mini Mental Status Exam) can also be used to assess an individual’s competency to consent.

Investigators must obtain informed consent prior to enrolling an individual as a research participant. The only exception to this requirement is when consent is specifically waived by the IRB. Consent must always be sought under circumstances that provide the prospective research participant (or their legally authorized representative) sufficient opportunity to fully understand the study related obligations, risks and benefits. Additionally, informed consent processes should be designed to minimize the possibility of coercion or undue influence.

An important responsibility of the IRB is determining the appropriateness of the informed consent process. Factors weighed in making this determination include where the consent process will take place, who will be obtaining the consent (e.g. the investigator, collaborator, or qualified designee), and any specific circumstances that may directly or indirectly influence the potential research participant’s decision-making. If the IRB determines that the potential research participant’s understanding of the research might be impaired due to the timing, location, or individuals participating in the proposed consent process, revisions to the proposed process will be required.

Prior to giving consent, the potential research participant (or legally authorized representative) must convey an appropriate level of understanding regarding the expectations of participation, research risks and research benefits. Consent without understanding is not informed consent. The information that is conveyed during the informed consent process must be in language understandable to potential research participants (or their legally authorized representatives). Informed consent processes and documents may not include any exculpatory language through which potential research participants (or their legally authorized representatives) are made to waive or appear to waive any of their legal rights. Informed consent must be obtained by an individual who is knowledgeable of the IRB regulations for informed consent and well versed in the research protocol. Additionally, individuals responsible for attaining informed consent from
potential research participants must complete appropriate IRB researcher training as described in Section 12.8 below.

**9.2 BASIC ELEMENTS OF INFORMED CONSENT**

Informed consent must be obtained from each potential research participant (or their legally authorized representative), in accordance with, and to the extent required by 45 CFR 46.116.

It is the responsibility of the IRB to validate that the following elements are present in the informed consent process and informed consent document(s).

1. Identification of the proposed study as research. Potential participants must be given the following information about the research study: the purpose(s) of the research, the expected duration of participation, the research procedures to be followed, and reasonably foreseeable research-related risks or discomforts that may be experienced by the participant. Any procedures which are experimental must be clearly identified.

2. A description of any benefit(s) directly derived from participation in the research study and/or a description of benefits that may reasonably be incurred by others as a result of new knowledge gained through the research.

3. A disclosure of appropriate alternative procedures or courses of treatment that may be advantageous to the potential research study participant.

4. A statement describing the extent (if any) to which confidentiality of records identifying the potential research study participant will be maintained.

5. A statement describing the availability of any medical treatment that will be made available to research participants who experience a research-related injury. This statement includes information about who will pay for the treatment and whether other financial compensation is available (for research involving more than minimal risk).

6. Identification of persons to contact for answers to questions about the research study and/or the individuals rights as a research participant. Identification of persons to contact should the research study participant experience a research-related injury.

7. A statement describing that participation in research is voluntary. Specifically noted in this statement is that there is (and will be) no penalty or loss of benefit for refusing to participate in the research. Also specifically noted is that persons who begin to participate in the research may discontinue their participation at any time without penalty or loss of benefits (to which they are otherwise entitled).

The IRB may request that the following additional elements of informed consent be applied, as appropriate.
1. A statement noting that the research related treatment(s) or procedure(s) may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2. A statement describing any anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.

3. A statement describing any additional costs that may be incurred by persons as a result of participation in the research.

4. A statement describing the consequences that might result if persons decide to withdraw from the research study. This statement should also include procedures for orderly termination of participation.

5. An assurance to potential research study participants that if significant new findings are developed during the course of the research (which may relate to the participant's willingness to continue participation), this new information will be shared.

6. A description of the approximate number of participants involved in the study.

### 9.3 Waiver 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 as previously described. Additionally, the IRB may waive the requirement for informed consent. The option to waive any or all of the requirements for informed consent can be exercised by the IRB if it finds and documents that:

1. The research involves no more than minimal risk to the participants; the waiver or alteration will not adversely affect the rights and welfare of the participants; the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

OR

2. 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 public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or 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.
9.4 DOCUMENTATION OF INFORMED CONSENT (SIGNED CONSENT)

Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

1. Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the research participant or the participant’s legally authorized representative. The form is signed at the time of consent, which must be prior to participation in any research activities.

2. A copy of the consent form must be given to the person signing the form.

3. The document of informed consent may be developed using either the full written consent format or a shortened written consent format. The shortened written consent document is appropriate when the elements of informed consent have been read to the prospective research participant (or the participant’s legally authorized representative). The following elements must be included in the consent process when the shorten written consent document is used.

   a. There must be a witness to the oral presentation.
   b. The IRB must approve the written summary of the oral presentation. This summary document must include 3 signature lines: for the research participant or their legally authorized representative, the witness, and the person actually obtaining the consent.
   c. The witness must sign both the short written consent document and a copy of the summary (that was presented orally).
   d. A signed copy of the summary and a signed copy of the short written consent document must be given to the research participant (or their legally authorized representative).

4. Written consent documents may be read to the prospective research participant (or the prospective participant’s legally authorized representative), but adequate opportunity must be provided for the individual to read the document before requesting a signature.

9.5 WAIVER OF DOCUMENTATION OF INFORMED CONSENT (WAIVER OF SIGNED CONSENT)

The IRB may exercise the option to waive the requirement for the investigator to obtain signed informed consent from some or all research participants (or their legally authorized representative) if one or both of the following conditions are met:

1. The only record linking the participant to the research would be the signed document of informed consent AND the principal risk associated with participation in the research would be the potential harm that might result from a breach of confidentiality. According to the Federal Regulations, research participants must be asked if they want
documentation linking them with the research. Participants who prefer to sign an informed consent document must be given this opportunity.

2. The research presents no more than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context.

When the documentation requirement is waived, the IRB may require the investigator to provide participants with a written description of the research and expectations of the research participants. In many instances, this statement will include many of the elements of informed consent presented in section 9.2.

9.6 REVIEW AND APPROVAL OF THE INFORMED CONSENT FORM

The IRB is responsible for reviewing and approving the informed consent document(s) prepared by the investigator. The informed consent document(s) must contain all of the required elements and meet all other requirements as described in this policy. The IRB will indicate that the informed consent document has been approved by affixing a certification stamp on each page. This certification stamp includes the date of approval and the expiration date. If the consent form is amended during the protocol approval period, the IRB will stamp the revised document with the date of the amendment and the expiration date.

The IRB must ensure that the required language for a valid authorization to release health information is included in a HIPAA (Health Insurance Portability and Accountability Act) Authorization form. The IRB may waive the requirement for an authorization or may alter the form or content of the authorization only in accordance with and as permitted by the HIPAA Privacy Rule (45 CFR 164.508). Such actions and the justification for them must be fully documented in the minutes of the IRB meeting where the action was taken or reported (if approved by expedited review).

9.7 PARENTAL PERMISSION AND ASSENT

See Section 10.1.1 for policies on parental permission and assent in research involving children.

9.8 SURROGATE CONSENT

This policy is designed to protect human participants from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent or who have an impaired decision-making capacity.

The regulations generally require that the investigator obtain informed consent directly from prospective research participants. Under appropriate conditions, investigators also may obtain informed consent from the prospective research participant’s legally authorized representative. The process of obtaining informed consent from a legally authorized representative is referred to as surrogate consent.
Surrogate consent may be obtained from a court appointed guardian or a health care agent named by the person in a Durable Power of Attorney for Health Care (DPAHC) document. Because not all DPAHC include provisions for surrogate approval for research participation, a careful review of the DPAHC document is warranted.

Surrogate consent may be requested and accepted only when the prospective research participant is incompetent 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 of incompetence must be made in accordance with the following two requirements:

1. The practitioner may determine after appropriate medical evaluation that the prospective research participant lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.

2. If the prospective research participant lacks decision-making capacity because of a diagnosis of mental illness, verification must be obtained through consultation with a psychiatrist or licensed psychologist.

The IRB will require investigators to conduct a competency assessment whenever there is the possibility of either impaired mental status or impaired decision-making capacity in prospective subjects. If feasible, the investigator must explain the proposed research to the prospective participant even when the surrogate provides legal consent. Under no circumstances may an individual (regardless of competency) be forced or coerced to participate in a research study.

9.9 CONSENT AND LANGUAGE BARRIERS

Researchers should prepare both English language and translated consent forms and study documents when proposals include the recruitment of non-English-speaking individuals. Additionally, the researcher should provide explanations for the translated documents and evidence that the translated documents are equivalent to the English forms. The IRB may consult with language experts or require a "back-translation" into English.

If a non-English-speaking participant is enrolled unexpectedly, researchers may rely on oral translations of the English language consent form and study documents. Extra care in the informed consent process must be demonstrated to ensure that the potential participant can demonstrate the appropriate level of understanding needed for consent. A notation in the research record (and on the English language consent form) should be included to identify the translator and document that the oral translation was provided. Additionally, the notation should include a statement from the translator indicating that the participant understood all the study specific elements required for consent. If the participant is a patient, an additional note about the translation should be recorded in the patient's medical records. Researchers should try to provide a written translation of the vital emergency contact information.

If the individual understands oral English but not written English, an impartial witness should document that the potential participant understands the project specific information necessary for consent.
10.0 VULNERABLE POPULATIONS

10.1 RESEARCH INVOLVING CHILDREN

Research involving children is governed by 45 CFR 45, Subpart D.

10.1.1 ALLOWABLE CATEGORIES

Research involving minor children as participants must be reviewed and categorized by the IRB into one of the following four groups.

Category 1 includes research that does not involve any physical or emotional risks greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This research is also categorized as minimal risk [45 CFR 46.404]. If the research is consistent with the attributes described for Category 1, only one parent or legal guardian is necessary for consent.

Category 2 includes research that involves greater than minimal risk but also presents the prospect of direct benefit to the individual participant [45 CFR 46.405]. The risks associated with participation in Category 2 research are justified because of the reasonable anticipation of direct benefit to the subjects. If the research is consistent with the attributes described for Category 2, consent is needed from one parent or legal guardian and assent is needed from the child.

Category 3 includes research that involves greater than minimal risk and no reasonable prospect of direct benefit to the participant. Research in category 3 has the potential to yield generalizable knowledge about the participant’s disorder or condition [45 CFR 46.406]. The participant risk for Category 3 research is slightly greater than minimal risk. The research intervention(s) or procedure(s) are reasonably commensurate with those inherent in the participant’s actual or expected medical, dental, psychological, social, or educational situations. If the research is consistent with the attributes described for Category 3, permission of either both parents or both legal guardians 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 is needed from the child.

Category 4 includes 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]. Research in this category must be approved by the Secretary of Health and Human Services and requires consent of both parents or legal guardian(s).
10.1.2  PARENTAL PERMISSION AND ASSENT

10.1.2.1  PARENTAL PERMISSION

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

Parents or guardians must be provided with the basic elements of consent as described in 45 CFR 46.116(a) (1-8) and any of the additional elements the IRB deems necessary. Permission from parents or legal guardians must be documented in accordance with and to the extent required by 45 CFR 46.117.

The IRB may determine that the permission of one parent is sufficient for research to be conducted (45 CFR 46.404 or 45 CFR 46.405). The IRB will document in the meeting minutes whether consent must be obtained from one or both parents.

Consent from both parents is required for research to be conducted under 45 CFR 46.406 and 45 CFR 46.407 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(d) (1-4) and if the IRB determines that the research protocol is designed for conditions or a participant population for which parental or guardian permission is not a reasonable requirements to protect the subjects (for example, neglected or abused children).

- An appropriate mechanism for protecting the minors 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 depends upon the nature and purpose of the research activities described in the protocol and the risk and anticipated benefit to the research participants. Additionally, the participant’s age, maturity, status, and condition will be considered when making this determination.

10.1.2.2  ASSENT FROM CHILDREN

Children should be given an opportunity to provide assent. The assent process should be tailored to the age, maturity, and psychological state of the children involved. Information presented to children should be easy for them to understand. In order to adequately convey information about the research to the child, a variety of documents and/or approaches may be used including verbal scripts (ages 7 - 11), written assent documents with revised language (ages 12 - 15), and a written assent matching the detail of an adult consent document (ages 16 - 17). Additionally, information may be conveyed using a variety of technology sources such as computer programs, CDs, videos, etc. Minor subjects 12 years of age or older must sign the assent document after the parent or legal guardian has given consent unless [45 CFR 46.404].
The IRB may waive the requirement for signed assent if it determines that one of the following three situations applies:

1. The research holds out the prospect of direct benefit to the participant (child) and this benefit is only available in the context of this research (e.g., new therapy when none is available).

2. The participant (child) is incapable, cognitively, mentally or emotionally of being reasonably consulted.

3. The IRB specifically waives the requirement.

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 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 premise is that children should not be forced to be research participants, even if parental consent is obtained.

The Assent Form
Researchers should develop assent documents that are age appropriate and study specific. Assent documents should be appropriate based on the typical child’s experience and level of understanding. The document should be appropriately respectful and convey all of the essential information about the study. The assent form should include the following elements:

1. Explanation of why the research is being conducted;
2. Description of what will happen and for how long (or how often);
3. Explanation of assent: the child can decide if he/she wants to participate or not participate in the research (it is OK to not participate and say “no”);
4. Explanation of any probable consequences that may result from participation (for example, if a study intervention will hurt, how bad will it hurt, how long will the pain last and how often will this happen);
5. Clear description of the child’s other choices (other options that do not include research);
6. Description of any good things that might happen (directly to the child or to other people) as a result of this research;
7. Information about any compensation for participation (or lack of compensation for participation);
8. Information about who can answer questions about the research.

The complexity and communication style of the assent document must be age appropriate. For younger children, the document should be shorter (limited to about one page) and may include pictures and a larger font. For older children and adolescents, the document should be longer, more detailed and more complex.
**Determination of a Minor’s Capacity for Assent**

The determination of capacity for assenting to participate in a research study will be made by the IRB based on the age (or age range), maturity level, and psychological state of the children or child recruited for participation. This judgment may be made for all of the children recruited for participation in a particular research protocol, or for each child (individually), as the IRB deems appropriate.

Under circumstances detailed in the Waiver of Informed Consent section of this manual, the IRB may waive the assent requirement. Additionally, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or legal guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), it may waive the informed consent requirements for parents or legal guardians, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided that this waiver is not inconsistent with Federal, State, or local law.

The choice of an appropriate mechanism for substituted judgment will depend upon the following elements:
- The nature and purpose of the research activities described in the protocol;
- The risk(s) and anticipated benefit(s) to the research participants;
- The potential research participants’ age and maturity,
- Specific aspects of the research;
- Federal, state and local laws.

When parental or legal guardian consent to participate in research is obtained, it must be documented in accordance with and to the extent described in the Informed Consent section of this manual. When a child's assent is required, the IRB will evaluate documentation procedures for appropriateness.

**10.1.2.3 CHILDREN WHO ARE WARDS**

There are specific limitations placed on research recruitment from the population of children who are wards of the State or any other agency, institution, or entity. These children can only be recruited to participate in research that involves greater than minimal risk and no prospect of direct benefit to individual participant, (but likely to yield generalizable knowledge about the subject's disorder or condition) in the following situations:

1. The research study is specifically related to the child’s status as wards.
2. The research is 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 either of the two conditions identified above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child). This advocate is **in addition to** any other individual who may be acting on behalf of the child as legal guardian or in *loco parentis*. The advocate must be an individual who agrees to
function in this role and who has the background and experience to act in the best interests of the child for the duration of the child's participation in the research. Additionally, the advocate must be an individual 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.

10.2 RESEARCH INVOLVING PREGNANT WOMEN, HUMAN FETUSES, AND NEONATES

[45 CFR 46, Subpart B; Federal Register: November 13, 2001 (Volume 66, Number 219)]

RESEARCH INVOLVING PREGNANT WOMEN OR FETUSES [45 CFR 46.204] 10.2.1

Pregnant women or fetuses may be involved in research 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. If there is no prospect of direct 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. The pregnant woman’s consent is obtained in accord with the provisions for informed consent 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).

5. The consent of the pregnant woman and the father is obtained in accord with the provisions for informed consent if the research holds out the prospect of direct benefit solely to the fetus. Exceptions to the requirement for the father’s consent include the father’s unavailability, incompetence (or temporary incapacity) or a pregnancy resulting from rape or incest.

6. All persons providing consent (points 4 and 5) are fully informed about the reasonably foreseeable impact of the research on the fetus or neonate.

7. If the pregnant female is a child, 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 not be involved in the decision making process concerning the timing, method, or procedures used to terminate a pregnancy.

10. Individuals engaged in the research will not have a role in determining the viability of a neonate.

10.2.1 Research Involving Neonates [45 CFR 46.205]

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

1. Preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates (as scientifically appropriate).

2. All persons providing consent are fully informed about the reasonably foreseeable impact of the research on the neonate.

3. Individuals engaged in the research will not have a role in determining the viability of a neonate.

4. The requirements of Neonates of Uncertain Viability or Nonviable Neonates (as described in the following section) have been met as applicable.

Neonates of Uncertain Viability. Until viability has been ascertained, a neonate may not be involved in research covered by this subpart unless the IRB determines that both of the following additional conditions have been met:

1. The research holds out the prospect of enhancing the neonate’s survival probability 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 which 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;

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 the provisions of permission and assent do not apply). 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. 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.

10.2.2 Research INVOLVING THE DELIVERED PLACENTA, DEAD FETUS OR FETAL MATERIAL

[45 CFR 46.206]

1. Research involving the delivered placenta; 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.

2. 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), the identifiable individuals are research participants and all pertinent sections of this manual are applicable.
10.2.3 Research Not Otherwise Approvable

[45 CFR 46.207]

The Secretary of the Department of Health and Human Services (DHHS) will fund research that does not meet the IRB requirements for Research Involving Pregnant Women or Fetuses or Research Involving Neonates only if:

1. 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

2. The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined that either the research in fact satisfies the conditions of Research Involving Pregnant Women or Fetuses, as applicable OR

   1) 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;

   2) The research will be conducted in accord with sound ethical principles; and

   3) Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

10.3 Research Involving Prisoners

Research involving prisoners is governed by 45 CFR 46, Subpart C.

10.3.1 Applicability

This policy applies to all biomedical and behavioral research conducted under the auspices of the University of Indianapolis involving prisoners as research participants. In addition to University of Indianapolis IRB approval, research protocols involving prisoners as research participants are subject to the Administrative Regulations of the Indiana Department of Corrections and any other applicable State or local law. [45 CFR 46.301]

10.3.2 Purpose

Because prisoners may be subjected to incarceration related constraints which could affect their ability to make truly voluntary and free research participation decisions, it is the purpose of this policy to provide additional safeguards for the protection of prisoners involved in research activities to which this subpart is applicable. [45 CFR 46.302]
10.3.3 COMPOSITION OF THE IRB

[45 CFR 46.304]

In addition to satisfying the general requirements detailed in the IRB section of this manual, the IRB must also meet the following requirements when reviewing protocols that involve prisoners as research participants:

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. When a research project is reviewed by more than one IRB, only one IRB involved in the review needs to satisfy this requirement.

10.3.4 ADDITIONAL DUTIES OF THE IRB

[45 CFR 46.305]

In addition to all other responsibilities prescribed for the University of Indianapolis IRB, the IRB will review and approve research involving prisoners only if it finds that:

1. the research falls into one of the following permitted categories [45 CFR 46.306]:
   
   a. a minimal risk study of the possible causes, effects, and processes of incarceration and / or a minimal risk study of criminal behavior that presents no more than an inconvenience to the participants;

   b. a minimal risk study of prisons as institutional structures or of prisoners as incarcerated persons that presents no more than an inconvenience to the subjects;

   c. research on conditions particularly affecting prisoners as a class of persons (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 participants.

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 an 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 participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides written acceptable justification to the IRB for following other research design procedures, control subjects must be selected randomly from the group of available prisoners who meet the participant selection inclusion and exclusion criteria.

5. the information is presented in language which is understandable to the participant population;

6. adequate assurance exists that parole boards will not take into account a prisoner's participation in the research when 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. when the IRB determines that follow-up examinations or medical care may be needed by individuals following their participation in the research, adequate provisions are made to inform participants about this availability and provide these services, taking into account the varying lengths of individual prisoners' sentences.

10.3.5 WAIVER FOR EPIDEMIOLOGY RESEARCH

The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

1. The study purpose is limited to describing the prevalence or incidence of a disease by identifying all cases or limited to describing the 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 has documented that the research presents no more than minimal risk and no more than inconvenience to the prisoner-participants.

AND

8. Prisoners are not a particular focus of the research.

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 for protecting the privacy of the research participants and maintaining the confidentiality of the data.

10.4 PERSONS WITH MENTAL DISABILITIES OR PERSONS WITH IMPAIRED DECISION-MAKING CAPACITY

Research involving persons who are mentally ill and/or who have impaired decision making capacity presents a unique human subjects’ protections challenge to the IRB because of this population’s vulnerability to coercion. This challenge is increased when the research includes greater than minimal risk; does not offer direct medical benefit to the participants; and includes a research design that calls for washout, placebo, or symptom provocation.

10.4.1 IRB COMPOSITION

The IRB membership must include at least one member who is an expert in the area of the research. Consideration may be given to adding another member who is a member of the population, a family member of such a person or a representative of an advocacy group for that population.

The IRB may utilize a consultant and experts as necessary to ensure that appropriate expertise is used in the review process.

10.4.2 APPROVAL CRITERIA

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

1. Only incompetent persons or persons with impaired decision making capacity are suitable as research participants. It is the investigator’s responsibility to demonstrate to the IRB a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as research participants. Incompetent persons or persons with impaired decision-making capacity may not be selected as research participants simply because they are readily available.

2. If the research presents some probability of harm, there must be a greater probability of direct benefit to the research participant. Persons with impaired decision-making capacity should not be recruited as participants for research that imposes a risk of injury unless the research is intended to directly benefit the participant and the probability of benefit is greater than the probability of harm.

3. Health care agents [appointed under Durable Power of Attorney for Health Care (DPAHC)], next of kin, or legally appointed guardians must be appropriately informed
about the research study (including participant benefits and risks) AND appropriately informed about the obligations of a surrogate decision maker. They must be told that the responsibility of a surrogate decision maker is to determine what the participant would do if competent. If the proposed participant’s likely determinations are unknown, the surrogate decision maker should be told to use the incompetent person’s “best interest” as the basis for judgment (regarding participation).

10.4.3 ADDITIONAL CONCERNS

Researchers and IRB members must be aware that decision-making capacity may fluctuate. For individuals with fluctuating decision making capacity or those with a diminishing 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 research participants and to determine if surrogate consent is warranted.

The IRB will require competency assessment evidence verifying sufficient decision making capacity when either impaired mental status or insufficient decision-making capacity in prospective participants is questionable (as a prerequisite to obtaining informed consent).

Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their surrogate decision maker. Under no circumstances may an individual be forced or coerced to participate in a research study.
11.0 COMPLAINTS, NON-COMPLIANCE, AND SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

11.1 COMPLAINTS

The Chair of the IRB and the Human Protections Administrator will promptly handle (or delegate staff to handle) all complaints, concerns, and appeals received by the IRB from investigators, research participants and others.

11.2 NON-COMPLIANCE

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

Non-compliance is defined as failure to comply with any of the regulations and policies described in this document. Non-compliance may be minor or sporadic or it may be serious or continuing.

Minor or sporadic non-compliance is defined as failure to comply with IRB policies, which (in the judgment of the IRB Chair and/or Human Protections Administrator) are administrative in nature. Examples of minor or sporadic non-compliance include turning in a report of an unanticipated problem a day late or failure to date a consent form.

Serious non-compliance is defined as failure to follow any of the regulations and policies described in this document, which (in the judgment of either the IRB Chair or the convened IRB) increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research conducted without prior IRB approval is considered serious noncompliance.

Continuing non-compliance is defined as a pattern of non-compliance which (in the judgment of the IRB Chair or convened IRB) suggests the 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.

If in the judgment of the IRB Chair and Human Protections Administrator, the reported non-compliance is not serious, not continuing, and the proposed corrective action plan seems adequate, no further action is required.

If in the judgment of the IRB Chair and Human Protections Administrator, the non-compliance is serious or continuing, a formal inquiry will be conducted.
If in the judgment of the IRB Chair and Human Protections Administrator, any report or allegation of non-compliance warrants suspension or termination of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the IRB Chair may terminate or suspend the research pending a subsequent review by the IRB.

11.3 INQUIRY PROCEDURES

A determination may be made that an inquiry is necessary by the IRB based on situations including (but are not limited to):

1. Research participants complain that their rights were (or are being) violated;
2. Report(s) are received suggesting that the investigator(s) is (are) not following the protocol as approved by the IRB;
3. Unusual and/or unexplained study-related adverse events;
4. An external (e.g., sponsor) audit;
5. Repeated failure of the investigator(s) to report required information to the IRB.

A subcommittee is appointed consisting of IRB members (and non-members if appropriate) to ensure fairness and expertise. The subcommittee is given a charge by the IRB, which can include any or all of the following activities (as appropriate):

1. Review of the protocol(s) in question;
2. Review of the external audit report (FDA and/or sponsor);
3. Review of relevant documentation, including (but not limited to) consent documents, case report forms, research participant’s (s’) investigational and/or medical files (as they relate to the execution of the study in question);
4. Interview of appropriate personnel;
5. Preparation of either a written or oral report describing the inquiry procedure findings and recommended actions;
6. Presentation of the report describing the inquiry procedure findings and recommended actions to the full IRB at its next convened meeting;

The IRB determines the appropriate actions after considering the report from the inquiry subcommittee;
The investigator is informed of the IRB determination(s) in writing.

11.4 SUSPENSION OR TERMINATION

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to research participants. Any suspension or termination of approval must include a written report describing the reasons for the IRB's action. A copy of this written report must be promptly delivered to the principal investigator, appropriate institutional officials, and as appropriate the sponsor and/or Department of Health and Human Services or Agency head.

11.4.1 WHEN STUDY APPROVAL IS TERMINATED BY THE IRB

In addition to stopping all research activities, any individuals currently enrolled as research participants should be notified that the study has been terminated. Procedures for withdrawal of enrolled subjects should reflect the rights and welfare of the participants. When participant follow-up procedures are permitted and/or required by the IRB (for example procedures necessary to ensure the safety of the participants), the participants must be provided with appropriate information describing these procedures. Any adverse events/outcomes must be reported to the IRB and the sponsor.

Failure to abide by the University of Indianapolis Policies and Procedures for the Protection of Human Subjects and Federal regulations may result in sanctions including (but not limited to):

1. Suspension or termination of IRB approval for a specific research protocol or for all research involving human participants in which the investigator participates.

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 related to any investigator-related IRB termination or suspension of research.

3. The OHRP and/or the FDA may elect to take institutional or individual actions including:
   - Withholding the IRB approval of all new University of Indianapolis studies;
   - Directing that no new participants be added to any ongoing studies;
   - Termination of all ongoing studies (except when doing so would endanger the participants); and/or
   - Notifying relevant state, federal and other interested parties of the violations.
4. Disciplinary action of the investigator or other personnel involved in a study, up to and including dismissal, pursuant to University policies and procedures.

Failure to secure necessary University of Indianapolis IRB approval before commencing human subjects research must be reported to the appropriate Dean and Provost for disciplinary action.

Investigators should also be aware that, in general, the University of Indianapolis indemnifies them from liability for adverse events that may occur in studies approved by the University of Indianapolis IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator personally liable for any damages related to these adverse events.

11.5 REPORTING

Unanticipated problems involving risks to research participants or others; serious or continuing noncompliance with regulations or the requirements or determinations of the IRB; and suspensions or terminations of IRB approval must be promptly reported by the IRB and the Human Protections Administrator to the:

1. Vice President for Research, Planning & International Partnerships;

2. Principal Investigator's immediate supervisor and Dean; AND

3. The Federal Office for Human Research Protections and any sponsoring department or agency head.

If the determination includes suspension of an investigator, the Federal OHRP, Division of Oversight Compliance must be notified by the University of Indianapolis IRB Office.

All appropriate institutional officials must be informed of the IRB's decision.
12.0 INVESTIGATOR RESPONSIBILITIES

Principal investigators are ultimately responsible for all aspects of the research process associated with their study protocol(s). Although the principal investigator (PI) may delegate research responsibilities to other members of the research team, the PI must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

Investigators who conduct research involving human participants must:

- Develop and conduct research that is in accordance with the ethical principles described in the Belmont Report;
- Develop a research plan that is scientifically sound;
- Develop a research plan that minimizes research participant risk;
- Include in the research plan sufficient resources for protecting human participants including (but not limited to) supervision, trained staff, and support services;
- Protect the rights and welfare of prospective research participants;
- Implement plans for monitoring the safety and security of collected data;
- Implement procedures for receiving and responding to complaints or requests for additional information about the research protocol;
- Ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by all members of the research team;
- Obtain and document informed consent as required by the IRB (ensure that individuals are not participating in the research prior to obtaining appropriate consent);
- Ensure that documentation of IRB research protocol approval has been obtained before commencement of the research;
- Comply with all IRB decisions, conditions, and requirements;
- Ensure that the IRB protocol approval is maintained throughout the duration of the research project (timely submission for continuing IRB review and approval);
- Report unexpected or serious adverse events to the IRB;
- Obtain IRB review and approval (in writing) before implementing changes to previously approved protocols and/or consent forms;
- Seek IRB assistance as needed for protocol specific issues (for example: determining if a protocol meets the criteria for research or determining if a protocol is exempt from review);
- Maintain current human research protections training.

12.1 INVESTIGATORS

12.1.1 PRINCIPAL INVESTIGATORS

At the University of Indianapolis, faculty or staff members with University-paid appointments may serve as the Principal Investigator on a research project involving human participants.
Adjunct faculty of the University and any investigator whose status is considered to be “in training” (i.e. students) may not serve as a Principal Investigator but may serve as a co-investigator.

The PI has ultimate responsibility for all of the research activities associated with the protocol.

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

12.1.2 STUDENT INVESTIGATORS

As learners, students have not yet developed the competencies for meeting the responsibilities of the Principal Investigator role. Student participation in research is designed to provide a mentored opportunity to “engage in the research process,” and it is through this opportunity that competency develops. Because research competency is not a student pre-requisite for conducting research, students must have a faculty sponsor who meets the University of Indianapolis principal investigator eligibility criteria and who will assume the responsibilities of the Principal Investigator.

12.1.3 RESEARCH TEAM

Members of the research team include the principal investigator (PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way. Although some members of the research team may receive compensation for their work as research team members, others many contribute to gain expertise or to accomplish other personal goals.

12.2 PROTOCOL DEVELOPMENT

The Principal Investigator must carefully develop a proposal for submission to the IRB. Throughout the proposal, the PI must be sure that the information presented on the various submission forms and documents is internally consistent. For example, the description of the study presented in the proposal must be consistent with the study description provided on the recruitment materials and the study description provided on the informed consent document.

The protocol submitted for IRB review must address all of the following elements (as appropriate):

1. Title of the study
2. Purpose of the study
3. Sponsor of the study
4. Results of previous related research
5. Subject inclusion/exclusion criteria
6. Recruitment Procedures (including exact copies of scripts, posters, etc)
7. Justification for use of any special/vulnerable subject populations
8. Study design (including, as needed, a discussion of the appropriateness of research methods)
9. Description of procedures to be performed
10. The possible/potential risks to the participants
11. Provisions for minimizing risks/managing adverse reactions
12. The anticipated benefits of the research
13. An assessment of the risk/benefit ratio
14. Circumstances surrounding the consent procedure
   a. Setting
   b. Participants autonomy concerns
   c. Language difficulties
   d. Vulnerable populations
   e. Procedures for documenting informed consent
   f. Obtaining assent from minors
   g. Using witnesses and/or translators
15. Document storage
16. Compensation to participants for their participation
17. Compensation for injured research participants
18. Costs to participants for their participation in the study
19. Costs to third-party payers because of participant’s participation
20. Provisions for protection of participant’s privacy
21. Description of the resources available to protect research subjects, including: supervision, number and training of staff, appropriate support services
22. Letters of cooperation from partnering agencies and/or organizations

Proposed consent/assent form (if applicable) must include or address:
1. The General Principles and Basic Elements of Informed Consent
2. Translated consent documents, as necessary, considering likely participant population(s)
3. University of Indianapolis IRB-approved formats for consent forms and assent forms
   or
4. Waiver of Consent conditions

The investigator must obtain departmental review and/or sign-off by the department Chair or appropriate first line supervisor.

If research is DHHS-sponsored, materials delivered to the departmental IRB reviewer must include the entire sponsoring application; if there is a significant variation between the DHHS application and the IRB protocol, the investigator must identify and justify the discordance.

Following departmental review and/or sign-off by department Chair or other appropriate institutional official, the investigator must submit the original and required copies of all materials to University of Indianapolis IRB Office.

Investigators should contact the University of Indianapolis IRB Office before submission of documents to determine the number of copies to be submitted.
12.3 Changes to Approved Research

Investigators must receive IRB approval before implementing any research protocol changes unless the changes are necessary to eliminate an immediate hazard to the research participant. If changes are made to eliminate an immediate hazard to the research participant, the IRB must then be notified immediately.

Minor changes (i.e., changes that do not involve increased risk or discomfort) may be authorized by the IRB Chair or Human Protections Administrator. The Application for Revision to a Previously Approved Protocol, a revised informed consent form (if applicable), and a copy of the approved protocol with the proposed changes highlighted, should be sent to Ulndy IRB Office. The IRB Chair or Human Protections Administrator will sign and return the Application for Revision to a Previously Approved Protocol to indicate approval.

IRB approved Applications for Revision to a Previously Approved Protocol do NOT extend the approval expiration date.

12.4 Continuing Review After Protocol Approval

Ongoing research studies must be reviewed by the IRB at least annually. The IRB may determine that a more frequent review is warranted based on a determination of participant risk. Subsequent IRB reviews must take place prior to the protocol expiration date which is noted on the approved protocol or most recent continuing review. The IRB approval for research projects that do not receive continuing review approval expires on the date indicated. After the expiration date, participant recruitment, enrollment and protocol activities must be suspended. If the research is DHHS-sponsored, the Agency must be notified.

It is the responsibility of the Principal Investigator (PI) to submit a timely continuing review application. As a courtesy, at approximately 60 and 30 days prior to the protocol expiration, the Human Protections Administrator will send the PI a reminder notice. The investigator should allow sufficient time for development and IRB review of renewal submissions. The "approval date" and the "approval expiration date" are listed on all IRB certifications.

The application for continuing review is submitted using the Project Update and Closure Form and selecting the “Continuing Review” option. The following information describing the past year research project progress (cumulative data must also be included after the first renewal) should be included:

1. Number of participants enrolled in the research project to date;
2. Number of participants who withdrew prematurely and a summary of the reason(s) for their withdrawal since the last IRB review;
3. Summary of adverse events and unanticipated problems involving risks to participants or others since the last IRB review;
4. Summary of relevant recent literature, interim findings, and amendments (or modifications) to the research since the last review;

5. Relevant multi-center trial reports;

6. Additional relevant information, especially information about risks associated with the research; and

7. A copy of a current informed consent document that has been signed by one research participant and (if appropriate) a copy of the proposed consent document that includes all newly proposed changes.

12.5 **REQUIRED REPORTS TO THE IRB**

1. Any unanticipated problem(s) involving risks to participants or others that occurs must be promptly reported (within ten working days) to the IRB chair. Investigators must promptly report any unexpected or serious adverse event in writing using the *Adverse Event Reporting Form*. This includes study-related injuries or events (such as previously unknown reactions that are more severe than mild) and expected or well-described reactions that are life-threatening or fatal.

2. Investigators must provide the information required for Continuing Review (*Project Update and Closure Form*) using the manner and frequency prescribed (for the individual protocol) by the IRB. According to federal regulations, continuing review must occur at least annually, however the specific timeframe for each individual protocol is determined by the IRB.

3. Investigators must notify the IRB and file a final progress report (*Project Update and Closure Form*) when an approved research project is completed. The final progress report includes the information listed above for continuing review of protocols for the last research project period. Once data collection has been completed and the final progress report has been received and reviewed by the IRB, the Principal Investigator is not required to submit any further reports of the research to the IRB.

12.6 **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 participant, a copy of the signed consent form must be stored securely by the PI. The signed letter of informed consent must additionally be placed in the participant’s medical record (if the participant is a patient and this requirement has not been waived by the IRB). A copy of the participant signed letters of informed consent must be retained by the PI for a minimum of *3 years after completion of the research*. 
12.7 CONFLICT OF INTEREST – INVESTIGATORS

All Investigators must follow the University of Indianapolis Conflict of Interest Policy. Investigators must identify for resolution under that policy’s specific procedure any conflict of interest associated with a study, including but not limited to their personal investment in or other financial relationship with a company that might profit from the study. If the Investigator is permitted to proceed with the study following review under that policy, the research consent form provided to subjects should include an appropriate description of any relationship that might be received as a potential conflict of interest. This information must be reflected in the consent form.

As part of the application process for IRB approval, all investigators must disclose any potential or real financial conflict of interest they may have as a result of the sponsorship for that study.

If the Conflict of Interest status of an investigator changes during the course of a study, the individual is required to declare this to the UIndy IRB Office.

12.8 TRAINING/ONGOING EDUCATION OF PRINCIPAL INVESTIGATOR AND RESEARCH TEAM

An important component of a comprehensive human research protection program includes education for all individuals working with research participants. The University of Indianapolis IRB provides training and on-going education for investigators, research team members, and students. This training includes the Collaborative IRB Training Initiative (CITI) online training modules and on-campus seminars and consultation opportunities. Human participant protections topics include (but are not limited to) research ethics, regulatory requirements associated with the conduct of research and institutional requirements associated with the conduct of research.

12.8.1 ORIENTATION

All Principal Investigators and members of their research team must review the University of Indianapolis Policies and Procedures for Human Research Protection, The University of Indianapolis submission guidelines and the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

12.8.2 INITIAL EDUCATION

The UIndy IRB Office maintains a subscription to the Collaborative IRB Training Initiative (CITI) online training program. This program is co-sponsored by the Collaborative IRB Training Initiative and the University of Miami. To satisfy the initial education requirement, the University of Indianapolis IRB has determined that each required module must be completed at a 75% competency level.

New research protocols and applications for continuing review will not be accepted from principal investigators who have not completed the initial education requirement [or the continuing education requirement once the initial education requirement has been satisfied].
While research protocols and applications for continuing review will be accepted and reviewed if the Principal Investigator holds a current certification of training, final approval will not be granted until all co-investigators and members of the research team have completed the initial education requirement [or the continuing education requirement once the initial education requirement has been satisfied].

12.8.3 IRB TRAINING FROM OTHER INSTITUTIONS

The University of Indianapolis IRB recognizes other institutions have well-established training programs in place that are comparable to our own. While all University of Indianapolis faculty, staff, and students must complete the CITI training, investigators from other institutions may be able to substitute IRB training from their institution in lieu of the CITI training if the following conditions are met:

- The research team member’s institution must have an IRB.
- The research team member must include with the protocol submission documentation of acceptable and current (within the past 2 years) IRB training
- The research team member must provide the IRB with a description of the training (or a web link to the training). The IRB Chair or the Human Protections Administrator will determine if the training sufficiently meets the University of Indianapolis requirements.

12.8.4 CONTINUING EDUCATION AND RECERTIFICATION

All investigators and members of their research team must maintain current Human Participants Protections training status. The University of Indianapolis IRB has determined that human participant protections education be completed every two (2) years. There are no exceptions to this requirement.

Investigators who have completed the CITI Basic Course may take the CITI Refresher Course to satisfy the continuing education requirement.

Investigators who have completed the Human Participants Protection Education for Research Team training (NIH training) may take the CITI Basic Course to satisfy this requirement.

Completion of the CITI Refresher Course only satisfies the continuing education requirement if the investigator has previously completed the CITI Basic Course because the Refresher Course is designed to be a follow-up to the Basic Course.

12.8.5 ADDITIONAL RESOURCES

Information is available on the University of Indianapolis IRB website to ensure that the campus community is apprised of current regulatory requirements, IRB policy, training opportunities and IRB committee meeting dates.
12.9 PARTICIPANT RECRUITMENT

Investigators are responsible for recruiting research participants in a manner that is fair, ethical and equitable. IRB approval is required for all recruitment procedures and materials. Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive. Exact copies of all recruitment materials including (but not limited to) recruitment scripts, posters, flyers and newspaper announcements must be submitted to the IRB for approval.

12.10 PAYMENT TO PARTICIPANTS

Payment to research participants may be viewed as an incentive or as a reimbursement for participation-related travel and other expenses. Payment for participation in research is not considered a research benefit. Regardless of the form of compensation, investigators must take care to avoid coercion. The amount of payments should reflect the degree of risk, extent of inconvenience, discomfort associated with participation, and/or “reasonable” compensation. 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 diminish the possibility of coercion or undue influence.

The consent form must describe the terms of payment and the conditions under which participants would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

If payment is administered through the University of Indianapolis, the Accounting Office requires identifying information to issue checks, cash, or gift certificates to payees. The consent form must inform subjects that they will be asked to provide their Social Security Number and/or verification of U.S Citizenship or Permanent Resident Status to receive payment.

If payment will be made using gift cards or gift certificates and if funds for purchasing these items will be reimbursed by the University of Indianapolis, participants must sign a form indicating that the gift card or gift certificate has been received.

12.11 INVESTIGATOR CONCERNS

Concerns or suggestions regarding University of Indianapolis’ Human Research Protection Program can be conveyed to any of the following individuals: University of Indianapolis Vice President for Research, Planning & International Partnerships, IRB Chair, IRB Human Protections Administrator, and/or IRB Committee Member. When appropriate, the Vice President for Research, Planning & International Partnerships will investigate the issue, convene the parties involved to form a response (when deemed necessary), and/or make necessary procedural or policy modifications (as warranted).
13.0 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

13.1 HIPAA BACKGROUND

The Health Insurance Portability and Accountability Act of 1996 is expansive federal legislation. One component of HIPPA is the Privacy Rule which includes regulations designed to protect the privacy of an individual’s health care information. HIPAA was effective as of April 14, 2003.

HIPPA provides individuals in the United States with a basic level of rights and protections (regarding their personal health care information). Depending on applicable state law, individuals may have additional rights.

13.2 EFFECTS OF HIPAA ON RESEARCH

Any research that is derived from a "covered entity" within the University of Indianapolis must comply with this law. As of October 2016, neither UIndy in toto nor any of its component units are declared HIPAA covered entities.

13.2.1 RESEARCH UNDER HIPAA

HIPAA defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." The HIPPA definition of research is identical to the definition found in the Common Rule (which is separate federal legislation designed to protect human subjects involved in research). The HIPAA legislation includes privacy standards for safeguarding an individual’s protected health information (PHI). Further information is available from the HIPPA website at NIH - HIPAA Privacy Rule, Information for Researchers.

13.2.2 HIPAA AND NEW DOCUMENTATION REQUIREMENTS

New research documents include a HIPAA authorization form, a waiver of authorization form, and a de-identification form.

13.2.3 PATIENT RIGHTS AND RESEARCH

Under HIPAA, patients have specific rights regarding their personal health information. Rights that may be related to the research participant role include the following. The right to:
- Receive a Notice of Privacy Practices;
- Access, inspect, and receive a copy of one’s own protected health information (PHI);
- Request an amendment to one’s own PHI;
- 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.
14.0 SPECIAL TOPICS

14.1 CERTIFICATE OF CONFIDENTIALITY

14.1.1 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."

Certificates of Confidentiality constitute an important tool to protect the privacy of research study subjects. Certificates are issued by the National Institutes of Health (NIH) 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 have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. 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. For more information, see the NIH Certificates of Confidentiality Kiosk.

Certificates are granted sparingly. The study's funding source, if any, is not relevant to the decision.

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).

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 subject's medical record that could lead to social stigmatization or discrimination; or
• information about a subject's 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 UIndy IRB Office help in applying for a certificate.

The IRB may require investigators to apply for a Certificate of Confidentiality.

14.1.2 LIMITATIONS

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research participants 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, a subject's threatened violence to self or others, or from reporting a communicable disease. If researchers intend to make such disclosures, this should be clearly stated in the informed consent form which research participants 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 participant if:

• the participant (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 (DHHS) request such information for audit, program evaluation or investigation of DHHS 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.

14.2 MANDATORY REPORTING

While preparing a research protocol, investigators must keep in mind that the State of Indiana mandates reporting to designated officials and/or agencies for the following:

• Chapter 1 Offenses Against the Family (Ind. Code § 35-46-1-13)
• Chapter 3 Adult Protective Services (Ind. Code § 12-10-3-9)
• Chapter 5 Duty to Report Child Abuse or Neglect (Ind. Code § 31-33-5)
• Chapter 7 Communicable Disease: Duty or Authority to Warn or Notify (Ind. Code § 16-41-7)
Investigators should consult these sources to determine if potential subjects should be advised of mandatory reporting requirements during the informed consent process.

**14.3 UNIVERSITY OF INDIANAPOLIS STUDENTS AND EMPLOYEES AS SUBJECTS**

When University of Indianapolis students and/or employees are recruited as potential research participants, researchers must guarantee additional safeguards for these individuals to diminish the likelihood of coercion. In all instances, research participation must be voluntary and free of coercion. Researchers must emphasize that an individual’s academic status, grades, or employment will not be affected by the research participation decision.

To minimize coercion, investigators should avoid the use of their students and employees in their research. Investigators should solicit participants for research using general strategies such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes taught by colleagues. Recruitment of research participants from a classroom should be conducted in ways that alleviate any perceived pressure to participate. For example, an investigator should present the recruitment script at the end of the class period to allow non-participating students the option of leaving without missing class content.

**14.4 STUDENT RESEARCH**

**14.4.1 USE OF PROFESSIONAL RESEARCH METHODS IN THE CLASSROOM SETTING**

In some courses students collect data by using professional research methods, even though the students' work is not expected to contribute to generalizable knowledge. When student use of research methods in courses involves no more than minimal research participant risk, the University of Indianapolis faculty member assumes the primary responsibility for assuring that the rights and welfare of all human participants are protected. Classroom activities that include the collection of data from human participants AND that are consistent with the following 6 elements will be viewed as “instructional” and not subject to a mandatory IRB review.

1. The course faculty member must meet the IRB training requirements prior to the collection of data from human participants.
2. The research review category for the classroom project must fall under the “Exempt” from full review category (Title 45 Code of Federal Regulations Part 46: Protection of Human Subjects).
3. The purpose of the student investigation is solely for the fulfillment of a course requirement.
4. Reports that include data derived from the data collection (either identifiable or summarized) will be limited to in-class presentations and papers.
5. Discussion and distribution of the data will be strictly limited to the classroom setting.
6. The faculty member assumes full responsibility for communicating to students ethical principles of research, reviews student research protocols, monitors students research activities and reports of findings, and assures that the student's own work does not violate human subjects’ protections.
It is strongly recommended that all course personnel involved in the collection and/or analysis of human participants’ data fulfill the University of Indianapolis IRB training requirement. If a class project fails to meet any of the above criteria, it is the responsibility of the course faculty member to file a review application with the IRB.

### 14.4.2 Independent Study, Thesis and Dissertation

Independent study, thesis and dissertation research activities meet the federal definition of human subjects’ research and must be independently submitted to the IRB. When students conduct research as a part of their program of study, the faculty member is ultimately responsible for the protection of the participants, even if the student is the primary researcher and actually directs the project. Advisers assume the responsibility for students engaged in independent research and instructors are responsible for research that is conducted as part of a course.

At the University of Indianapolis, students may not be identified as the Principal Investigator. All students must have a faculty member sponsor or advisor who fulfills the principal investigator eligibility criteria.

### 14.5 Oral History

General principles for evaluating Oral History activities include the following:

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 DO 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.

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) DO constitute "research" as defined by HHS regulations at 45 CFR part 46.

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

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 WOULD constitute 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 UIndy IRB Office to determine if their oral history project requires IRB review.

14.6 RESEARCH INVOLVING CODED PRIVATE INFORMATION

University of Indianapolis policy regarding research involving coded private information is based on the OHRP guidance document entitled Guidance on Research Involving Coded Private Information or Biological Specimens. This document provides guidance in the following areas:

- Determining when research involving coded private information is or is not research involving human participants (as defined under HHS regulations for the protection of human research subjects 45 CFR 46).
- Reaffirming that (under certain limited conditions) research involving only coded private information is not human subjects’ research.
- Clarifying who is primarily responsible for determining when and if human participants are involved in research.

For purposes of this policy, coded means that:

1. 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 pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); AND
2. a key to decipher the code exists, enabling linkage of the identifying information to the private information.

Under the definition of human participant in Section 2 of this policy, obtaining identifiable private information for research purposes constitutes human participants research. Obtaining means receiving or accessing identifiable private information for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information already in the possession of the investigator.

In general, private information IS considered to be individually identifiable when this data can be linked to specific individuals either directly or indirectly using coding systems. Private information is NOT considered to be individually identifiable when this data cannot be linked to specific individuals either directly or indirectly through coding systems.
Research involving only coded private information does not fit the criteria for human subjects research if the following conditions are met:

(1) The private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals;

AND

(2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertain because:
   (a) the key to decipher the code was destroyed before the research began;
   (b) 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 agreement);
   (c) 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
   (d) 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 about living individuals under one of the conditions cited in 2(a)-(d) above may (1) unexpectedly learn the identity of one or more living individuals, or (2) for previously unforeseen reasons now believe that it is important to identify the individual(s). If the investigator knows (or may be able to readily ascertain) the identity of the individual(s) to whom the previously obtained private information pertain, the research activity now involves human participants. Unless this human participant research is determined to be exempt (See Section 7.2), IRB review of the research is required. Informed consent from the participant is also required unless the IRB approved a waiver of informed consent (See Section 9.3).

14.6.1 WHO DETERMINES WHETHER CODED PRIVATE INFORMATION CONSTITUTES HUMAN SUBJECTS RESEARCH

The investigator in consultation with the IRB Chair or Human Protections Administrator will determine if the research involving coded information 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 proposal to the IRB, 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.