INSTITUTIONAL REVIEW BOARD MANUAL

Effective January 21, 2019

Institutional Review Board

I. PURPOSE

Indiana Wesleyan University (IWU or "the institution") is committed to the protection of the rights and welfare of human subjects in all research, class projects and related activities. The Institutional Review Board (IRB or "the Board") is guided by the standards of U.S. government agencies (Code of Federal Regulations Title 45, Part 46) and ensures institutional compliance with all federal and state regulations regarding human subjects' research. No research involving human subjects at Indiana Wesleyan University may be executed by IWU faculty, staff, students or external investigators without IRB approval. IRB approval is also required for research conducted by IWU community members (faculty, staff and students) with human subjects at locations external to the university.

Using federal standards as a guide the IRB will seek to:

1. Ensure the protection of human subjects involved in research projects carried out by faculty, staff, and students.

2. Evaluate both risks and benefits of research.

3. Ensure that research conducted by IWU faculty, staff, students and external investigators meets the standards required by governmental agencies thereby protecting participants, investigators and the institution.

The Board's sole concern is protecting the safety, welfare and rights of human research subjects. Research methodology will not be evaluated so long as it does not impact risk and ethical issues. Approval of this Board is not an endorsement of the research techniques, results or conclusions drawn from the research.

II. DEFINITIONS

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected is deemed not to be research.

A **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Generalizable Knowledge is knowledge that is intended to be applicable and/or shared beyond the populations or situations being studied. Generalizable knowledge is likely to apply to all

people (or all of the type being studied), given roughly similar circumstances. Research designed to develop or contribute to generalizable knowledge may include one or more of the following:

- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
- The knowledge contributes to an already established body of knowledge
- Other investigators, scholars, and practitioners may benefit from this knowledge
- Publications including journals, papers, dissertations, and master's theses

The **Investigator** is the person who is accountable for the proposal performance and satisfactory completion of a research project. A student may be an investigator.

A **Research Advisor** is a person who is responsible for supervision of a student research project to assure that it will be carried out in a professional manner. The research advisor will ensure that the research will conform to the moral and ethical standards of Indiana Wesleyan University as well as comply with all IWU and Federal regulations regarding human rights. A research advisor shall be a faculty member (full-time or adjunct) or a full-time employee of IWU.

No Risk means there will not be any risk (including mental or physical injury) to human subjects in any area of the investigation. Observations of public behavior, use of public information, and some uses of anonymous data commonly involve no risk, but note that data anonymity does not necessarily mean that there is no risk to the subject in the study.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Moderate Risk means the research may potentially produce some harm to the subject in his/her physical, mental, social, emotional or spiritual state. The research may involve some deception of subjects as long as it does not violate appropriate ethical codes or guidelines.

Informed Consent means the knowing consent of an individual (or if a minor, his/her legally authorized representative such as parent, guardian, conservator, etc.) to participate in research. The person from whom the consent is sought must be given sufficient details in language he/she can understand to arrive at a reasonable decision. This includes the purpose of the project, procedures that will be used, time period of the project, anticipated risks and/or benefits, the subject's right to terminate participation at any time, any cost or benefit to the participant, confidentiality of the data, assurance that the subject's decision to participate or not participate in the study will have no undue effect on his/her standing, and details regarding authorization for access to the subject's personal records. All projects require the consent of participants, either through signed consent documents or implied consent associated with certain surveys. All consent forms must contain the following statement: "I participate of my own accord in this research project and release any claim to the collected data, research results, publication of or commercial use of such information or products resulting from the collected information."

Exempt from Further Review is a level of determination by the IRB for human subjects' research that falls in specific categories as outlined in "Section V. Scope."

An **Expedited Review** is a level of review that may be used to review research projects that present no more than minimal risk to a subject (not exceeding risk ordinarily encountered in daily life) as detailed in "Section V. Scope." Expedited research is typically reviewed by the IRB chairperson plus one or two Board members.

A **Full Review** is a level of review that is required for all human subjects' research projects that are not exempt from further review or eligible for expedited review. Any research that involves more than minimal risk to subjects requires a full review. Any research which involves fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or who may be high risk must be provided a full review. Research that includes children (persons under 18 years of age) requires full review. Full review involves the entire Institutional Review Board and may require a meeting of the Board. A two-thirds majority is required to approve a project subject to full review.

The term **Vulnerable (to coercion or undue influence)** is not included as a definition but is updated as a criterion (46.111(b)) for approval of research. Children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons are given as examples of subjects likely to be vulnerable to coercion or undue influence. The Final Rule no longer includes pregnant women or handicapped and physically disabled individuals as examples of populations potentially vulnerable to coercion or undue influence. The Final Rule uses the term "individuals with impaired decision-making ability" to replace "mentally disabled persons." The vulnerability of the subjects in research studies should be considered as a function of the possibility of coercion or undue influence.

An **Emancipated Minor** is a person who is not legally an adult but who, because he or she is married, in the military, a parent, financially independent or otherwise no longer dependent on parents or guardians, makes adult decisions and exercises general control over his or her own life. Therefore, in certain cases, an emancipated minor may not be required to obtain parental/guardian permission to participate in a research proposal as a human subject. State and national laws vary in specific interpretations of the rule.

A **Conflict of Interest** is a circumstance, relationship, commitment, or interest that constitutes a moral hazard.[1] Conflicts of interest may be related to the researcher, the research advisor, anyone else involved in the research or an IRB member. The common moral hazard is that the researcher, research advisor or anyone else involved in the research will compromise the research, in design or execution, in order to obtain a desired outcome. A financial conflict of interest, where the researcher's or research advisor's income or future income depends on the outcome of the research, is one form of conflict of interest, but not the only one. Conflicts of interest are not necessarily prohibitive, but they must be disclosed and, when present, protected against in research design. The IRB is responsible to protect human subjects from harm resulting from conflicts of interest and to protect the integrity of the scholarly process.

[1] Fiore, Robin N. (2014). CITI module, *Conflicts of Interest Involving Human Subjects*.

Broad Consent is a new concept presented in 46.116(a) and (d) which addresses elements of consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (blood, cells, etc.). It involves seeking prospective consent to unspecified future research. Broad consent may be obtained only for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Broad consent will be an optional alternative that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, having an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study. (Federal Register, Vol. 82, No. 12, p 7150)

Clinical Trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. The definition of clinical trial should be used for determining which studies require posting of the IRB-approved consent form used to enroll subjects.

Deception is not included in the definitions section of the Final Rule but under 46.104(d)(3)(iii) in regard to Exemption Number 3; it specifies that "this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research."

The **Final Rule** was written by a group of Federal departments and agencies to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

An **Identifiable Biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator.

Identifiable Private Information is private information for which the identity of the subject is or may readily be ascertained by the investigator.

Interaction includes communication or interpersonal contact between investigator and subject.

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

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

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

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

Key Information is undefined but is an important regulatory term. Key information must be prioritized by appearing at the beginning of the informed consent and be presented first in the consent discussion. According to the Final Rule's preamble (*Federal Register*, Vol. 82, No. 12, p 7214), a brief description of five elements at the beginning of the consent form, and informed consent process, would encompass the required key information. The five key elements are:
1. The fact that consent is being sought for research and participation is voluntary.
2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research.
3. The reasonably foreseeable risks or discomforts to the prospective subject.
4. The benefits to the prospective subject or to others that may reasonably expected from the research.
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

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

A **Limited Review** ensures that adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data in the exemption categories in the final rule that are predicated on the need for some type of privacy safeguards.

Practicably appears in the consent waiver and alteration sections of the revised rule (46.116(e)(3) and (f)(3)). It is undefined but is recommended to be interpreted as impracticable to perform the research not impracticable to obtain consent due to financial or administrative burdens, without the waiver or alteration.

Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Secondary Research Use is not defined in the regulations but is referred to as re-using (for research purposes) identifiable and non-identifiable information and biospecimens that are collected for some other "primary" or "initial activity" (such as from research studies other than the proposed research study). The information or biospecimens that are used for secondary research would generally be found by the investigator in: records, archives, information systems, databanks (in the case of information), or tissue repositories. There is no requirement that the

information and biospecimens must be pre-existing at the time that the investigator begins a research study.

Written or in Writing refers to writing on a tangible medium (e.g., paper) or in an electronic format. The definition does not preclude the possibility that consent forms could be in media other than paper or electronic formats and still meet the requirements of the Common Rule.

III. STRUCTURE

The Code of Federal Regulations (Title 45, Part 46.107, "IRB membership") guides the design of the IRB. Board membership is drawn from each of the Principal Academic Units (PAUs) of the university (College of Arts & Sciences, College of Adult & Professional Studies, Wesley Seminary, School of Nursing, School of Health Sciences and the Graduate School). The IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by IWU. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB may not consist entirely of members of one discipline. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB shall include at least one member who is not otherwise affiliated with IWU and who is not part of the immediate family of a person who is affiliated with IWU.

An IRB member with a conflicting interest may not participate in the IRB's initial or continuing review of any project except to provide information requested by the IRB. (See Section XVI. "Conflicts of Interest" for more information.)

The IRB may, in its discretion, 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. These individuals may not vote with the IRB.

All IRB members must successfully complete the CITI Program's "IRB Members-Basic/Refresher-Basic Course" (13 modules). The course can be accessed at https://www.citiprogram.org/index.cfm?pageID=14. The required modules for the "IRB Members-Basic/Refresher-Basic Course" are:

Belmont Report and Its Principles (ID: 1127)
History and Ethical Principles-SBE (ID: 490)

Defining Research with Human Subjects-SBE (ID: 491)
The Federal Regulations-SBE (ID: 502)
Assessing Risk-SBE (ID: 503)
Informed Consent-SBE (ID: 504)
Privacy and Confidentiality-SBE (ID: 505)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)
Conflicts of Interest in Human Subjects Research (ID: 17464)
Hot Topics (ID: 487)
The IRB Member Module: "What Every New IRB Member Needs to Know" (ID: 816)
Basics of Information Security, Part 1(ID: 1423)
Basics of Information Security, Part 2(ID: 1424)

The training must be complete prior to reviewing any human subjects' research proposals. IRB members must file a copy of the certification of completion of the training with the IRB office. Certifications are valid for four years after which IRB members must renew their certification by taking the refresher course.

IV. FUNCTION

The Board will uphold the Code of Federal Regulations Title 45, Part 46.108, "IRB functions and operations" and function following the guide of the Code of Federal Regulations Title 45, Part 46.103, "Assuring compliance with this policy." Board members will review proposals upon receipt from the Chair or the Chair's designee and submit their reviews to the IRB office. Approval of projects subject to full review will be granted by a two-thirds majority agreement of the Board.

V. SCOPE

The IRB has purview over all research that involves human subjects. The following sections detail the pattern of review as indicated by the nature of the research project.

A. **Research that the IRB may determine to be exempt from further review or require limited review**

Some types of research conducted by students and employees of Indiana Wesleyan University or conducted by outside investigators at IWU may be exempted from further review by the Board. The IRB may determine that research which falls within one of the following categories is exempt from further review if the subjects are eighteen years of age or older:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The Final Rule revised this category to include visual or auditory recording as research methods. Surveys also cannot include collection of biospecimens or interventions, as those additional activities would disqualify the research from this category. When the research includes children, Category 2 still does not allow surveys or interviews or the observer participating with children (public behavior observation without intervention is permitted). Category 2 requires Limited Review.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective

agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
Category 3 requires Limited Review.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA for the purposes of ''health care operations'' or ''research'' or for ''public health activities and purposes'' as those terms are defined in HIPAA; or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with the E-Government Act of 2002, the Privacy Act of 1974, and the Paperwork Reduction Act of 1995.
Category 4 requires Limited Review.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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.

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 found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the following determinations:
(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained.
(ii) Broad consent is appropriately documented or waiver of documentation is appropriate; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;
(ii) Documentation of informed consent or waiver of documentation of consent was obtained;
(iii) An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent; and
(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
Category 8 requires Limited Review.

B. **Research that may be approved by expedited review**

Research that presents no more than minimal risk to a subject (not exceeding risk ordinarily encountered in daily life) may be approved by expedited review if it falls into one of the following categories:

1. Collection of hair and nail clippings in a non-disfiguring manner, deciduous teeth, and permanent teeth if patient care indicated a need for extraction.

2. Collection of excreta and external secretions including sweat, decannulated saliva, placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects eighteen years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing, sensory acuity, electrocardiography, electroencephalography, and electroretinography. This does not include exposure to electromagnetic radiation outside the visible range, for example x-rays or microwaves.

4. Collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an eight- week period and no more often than two times per week from subjects eighteen years of age or older and who are in good health and not pregnant.

5. Collection of both supra-and sub gingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens or diagnostic specimens when the identity of the subjects is known.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, game theory and cognition, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

C. **Research that requires full review**

Research that involves more than minimal risk or is not covered by the exempt from further review and expedited review categories listed above will require full review.

Any research proposal that involves vulnerable populations e.g. children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons or other subjects likely to be vulnerable to coercion or undue influence must be provided full review. Research that includes children (persons under 18 years of age and including emancipated minors) requires full review.

D. **Low risk, non-publishable classroom research**

Projects that will be conducted solely within the structure of a course and do not extend beyond the termination of the course may not require the completion of a proposal to the IRB if such projects are not meant to contribute to "generalizable knowledge." Classroom research that uses only secondary data with no personal identifiers does not require IRB review or approval if the requirements of Exemption Category Number 4 are met.

Classroom research in which primary data are gathered may be divided into two general types: (1) Projects in which the learning outcomes, methodologies, and general procedures are determined by the faculty and/or student, and (2) Projects in which the learning outcomes, methodologies, and general procedures are determined as part of a centralized course and program design by the institution. In either type, the protection of human subjects must remain imperative. Investigators may still wish to submit proposals to the IRB for review even if all the classroom research requirements are met.

Type 1 Classroom Research

The following guidelines (which should be stated in the class syllabus) must be met for a Type 1 project to qualify as low risk, non-publishable classroom research:

1. The class instructor must have successfully completed the CITI Program's Human Subjects Research course. For most who take the course, the "Social and Behavioral Research Investigators" group is the appropriate one to sign up for; the other option is "Biomedical Research Investigators." See Section VI. TRAINING FOR PROTECTING HUMAN RESEARCH PARTICIPANTS for a list of required modules. The instructor must file a copy of the certification of completion of the training with the IRB office prior to the commencement of the classroom projects. Certifications are valid for four years after which the instructors must renew their certification by taking the refresher course. The instructor is responsible for the protection of human subjects who participate in said classroom projects.

2. The project must be part of a course requirement for a student enrolled at IWU. The principal purpose of the project must be as a learning experience in research methods and procedures.

3. There must be no intent to produce generalizable knowledge or disseminate information about the project outside the IWU campus.

4. The project must not involve children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, or other subjects likely to be vulnerable to coercion or undue influence. Populations subject to "undue influence" (e.g. college classes, employees, interest groups, clubs, Sunday School classes, and /or Bible study groups) may be considered "vulnerable" as well, depending on the nature of the project.

5. The project must present no more than minimal risk to a subject (i.e. not exceeding risk ordinarily encountered in daily life).

6. The project must not bring discomfort to subjects (e.g. from discussion topics) nor may it put participants at risk if confidential information is disclosed. The project must not contain any invasive elements (e.g. intense physical exercise).

7. The project must not involve any deception. Potential participants must be made fully aware of their involvement in the project and how collected data will be managed.

If all seven points above cannot be met and the project involves human subjects, then a proposal must be filed with the IRB.

Type 2 Classroom Research

The following guidelines must be met for a Type 2 project to qualify as low risk, non-publishable classroom research:

1. The project design as specified in the required curriculum must have been reviewed by the appropriate Curriculum Committee. At least two members of the Curriculum Committee must have successfully completed the CITI Program's Human Subjects Research course. For most who take the course, the "Social and Behavioral Research Investigators" group is the appropriate one to sign up for; the other option is "Biomedical Research Investigators." See Section VI. TRAINING FOR PROTECTING HUMAN RESEARCH PARTICIPANTS for a list of required modules. The Curriculum Committee members must file a copy of the certification of completion of the training with the IRB office prior to the commencement of the classroom projects. Certifications are valid for four years after which certifications must be renewed by taking the refresher course. Each member who has completed the training must file a copy of the certification of completion of the training with the IRB office prior to reviewing any project curriculum. The committee is responsible for the protection of human subjects who participate in said classroom projects.

2. The project must be part of a course requirement for a student enrolled at IWU. The principal purpose of the project must be as a learning experience in research methods and procedures.

3. There must be no intent to produce generalizable knowledge or disseminate information about the project outside the IWU campus or the organizations in which the research occurred. All personal identifiers must be removed from research data used in papers, presentations, and proposals.

4. The project must not involve children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, or other subjects likely to be vulnerable to coercion or undue influence. Populations subject to "undue influence" (e.g. college classes, employees, interest groups, clubs, Sunday School classes, and /or Bible study groups) may be considered "vulnerable" as well, depending on the nature of the project. The Curriculum Committee shall determine for each project if a population is considered vulnerable.

5. The project must present no more than minimal risk to a subject (i.e. not exceeding risk ordinarily encountered in daily life).

6. The project must not bring discomfort to subjects (e.g. from discussion topics) nor may it put participants at risk if confidential information is disclosed. The project must not contain any invasive elements (e.g. intense physical exercise).

7. The project must not involve any deception. Potential participants must be made fully aware of their involvement in the project and how collected data will be managed.

If all seven points above cannot be met and the project involves human subjects, then a proposal must be filed with the IRB.

VI. TRAINING FOR PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Effective July 1, 2017, all investigators and research advisors must successfully complete the CITI Program's Human Subjects Research course (11 modules). CITI Certification must be

submitted with the proposal form. The course can be accessed at https://www.citiprogram.org/index.cfm?pageID=14. For most who take the Human Subjects Research course, the "Social and Behavioral Research Investigators" group is the appropriate one to sign up for; the other option is "Biomedical Research Investigators." The following are the required modules in the Social-Behavioral-Educational (SBE) Research course:

Belmont Report and Its Principles (ID: 1127)
History and Ethical Principles-SBE (ID: 490)
Defining Research with Human Subjects-SBE (ID: 491)
The Federal Regulations-SBE (ID: 502)
Assessing Risk-SBE (ID: 503)
Informed Consent-SBE (ID: 504)
Privacy and Confidentiality-SBE (ID: 505)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)
Conflicts of Interest in Human Subjects Research (ID: 17464)
Basics of Information Security, Part 1(ID: 1423)
Basics of Information Security, Part 2(ID: 1424)

Depending on the research being conducted, additional Human Subjects Research modules may be requested by the IRB, particularly if the research involves students, protected populations such as children and prisoners, or will be conducted internationally. Principal Investigators and research advisors are encouraged to contact the IRB if they have questions about which additional modules may be applicable to their research. These modules include (among others):

Vulnerable Subjects - Research Involving Prisoners (ID: 8)
Vulnerable Subjects - Research Involving Children (ID: 9)
Vulnerable Subjects - Research Involving Pregnant Women, Fetuses, and Neonates (ID: 10)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)
Avoiding Group Harms - International Research Perspectives (ID: 14081)
Research with Decisionally Impaired Subjects (ID: 16610)
Research with Critically Ill Subjects (ID: 16592)
Gender and Sexuality Diversity (GSD) in Human Research (ID: 16556)
Research with Persons who are Socially or Economically Disadvantaged (ID: 16539)
Research with Older Adults (ID: 1652)
Illegal Activities or Undocumented Status in Human Research (ID: 16656)
Research Involving Subjects at the End of Life (ID: 16658)
Research with Subjects with Physical Disabilities and Impairments (ID: 16657)

Copies of the certification of completion of the training for all investigators and research advisors must be included with the proposal that is submitted to the IRB office. **Proposals will be returned if certifications are omitted from the proposal.** Certifications are valid for four years after which investigators and research advisors must renew their certification.

VII. PROPOSAL SUBMISSION

As detailed in "Section V. Scope" above, human subjects' research requires IRB approval. The approval process begins with the submission of a complete proposal using the *IRB Proposal Form (March 2017)* and as described further in the document *Guidelines for the Preparation of a Proposal*. Proposals should be submitted as early as possible prior to the intended date for commencement of research activities. Some proposals may require a Board meeting. Approval can usually be granted within two to three weeks of receipt of the application; however, the IRB does not guarantee approval within a certain period of time from submittal of application. Factors that affect approval time include the level of review, quality of the proposal, complexity of the proposal, the extent and magnitude of comments from the Board and the completeness and timeliness of the response to the Board's review by the researcher.

VIII. PERMISSIONS

Subsequent to IRB approval, any research proposals that incorporate survey research including 100 or more IWU faculty, students, or staff must be reviewed by the academic leadership of the involved principal academic unit(s) (PAU[s]). Once the project has been approved by the IRB, the IRB will act as liaison in obtaining permission from the PAU. The IRB will inform the Principal Investigator of IRB approval and PAU authorization. Authorization documents will be kept on file with the IRB at IWU. In the event that the PAU leadership does not support the project moving forward an explanation will be provided to the Principal Investigator within a timely manner.

IX. RESPONSIBILITIES OF INVESTIGATORS

Investigators are responsible for following the research protocol approved by the IRB. Any change in research protocol must be approved by the IRB prior to execution. The IRB-assigned proposal number must be included in all correspondence with the IRB.

X. SUSPENSION OR TERMINATION OF APPROVAL

The IRB has the authority to terminate or suspend a project if it is found that the protocol approved by the IRB has been changed without permission of the IRB. The IRB may suspend a project if complaints or other indicators suggest the need for further review.

XI. EXTENSION OF APPROVAL

Each IRB approval is of limited duration (commonly one year) with a specified expiration date. If the project will extend beyond the approval expiration date, a new proposal may be requested by the IRB for review.

XII. RECIPROCITY

The IWU IRB does not automatically accept another institution's IRB approval in lieu of review of a proposal submitted to the IWU IRB. The IWU IRB reserves the right to request a proposal

using the IWU IRB proposal template. The Indiana Wesleyan University IRB requires copies of the approvals by other institutions' IRBs (when applicable) as part of the project file.

XIII. EMANCIPATED MINORS

The laws of the state in which the research is conducted will govern IRB decisions regarding whether emancipated minors can complete consent forms in lieu of parental/guardian consent.

XIV. ADVERSE EVENTS AND UNANTICIPATED PROBLEMS INVOLVING RISKS TO HUMAN SUBJECTS RESULTING FROM PARTICIPATION IN A RESEARCH STUDY

Federal regulations (45 CFR 46.103 [b] [5]) require investigators to report unanticipated problems, complications or complaints to the IRB in a timely fashion. The Department of Health and Human Services defines an adverse event as "an undesirable and unintended, though not necessarily unexpected, result of therapy or other intervention." (http://archive.hhs.gov/ohrp/irb/irb_glossary.htm) The scope of the definition includes any "unanticipated problems involving risks to subjects or to others" (http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/) in medical and non-medical research alike.

Under these federal requirements, investigators must report to the IRB in writing the nature of the problem within five working days of the occurrence. In addition, any injury or physical or emotional harm to a participant must be reported immediately to the IRB. Other examples include, but are not limited to, a breach in confidentiality or privacy, problems with recruitment and/or the consent form process, noncompliance with federal regulations or IRB policies, complications or complaints occurring during the research, or any other problem that presents changes in the risk-benefit ratio and affects the rights, welfare and safety of subjects. A separate report must be filed for each incident summarizing the problem or difficulty encountered along with a statement by the investigator indicating whether a change in the protocol and/or consent form is warranted and whether, in the investigator's opinion, the adverse event was related to the research activity. Reports shall include the name of the investigator, IRB protocol number, study title, name(s) or code number(s) of subject(s) and others affected by the event, and the date and location of the event.

Following receipt of an adverse event report, the IRB will review the information to determine whether any further actions, beyond any changes or amendments to the protocol that are proposed by the investigator, are warranted. The IRB reserves the right to review and approve all the proposed changes and determine whether the study should be continued as originally approved, modified, or discontinued. Further, the IRB is required to report to the Associate Provost and the US Department of Health and Human Services Office of Human Research Protections (HHS-OHRP) and, when applicable, any sponsoring agency, all adverse events that caused injury to human subjects or other major effects that involved unanticipated risks or problems. Investigators must also comply with any reporting requirements in the protocol itself or as stipulated by the sponsoring agency in grant documents or agency regulations.

XV. RETENTION OF RECORDS

Electronic copies of all signed consent forms must be sent to the IRB in one electronic file at the completion of the study. All other study documents (hard copy or electronic) must be retained for a minimum of three years after close of the study by the principal investigator.

The IRB shall prepare and maintain adequate documentation of IRB activities per 45CFR46.115, "IRB records." including: copies of all research proposals reviewed, approved sample consent documents, reports of injuries to subjects, minutes of IRB meetings, and copies of all correspondence between the IRB and principal investigators.

IRB records shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

XVI. CONFLICTS OF INTEREST

IRB Members

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Conflicts of interest include, but may not be limited to, the following:
1. The IRB member is currently engaged, or expects to be engaged, in the human subjects' research project under review.
2. The IRB member has a direct financial interest in the principal investigator or the entity funding the research proposed by the principal investigator.
3. The IRB member and the principal investigator of the application under consideration share an immediate (rather than extended) familial relationship.
4. The IRB member has other reasons to feel that she or he cannot render an independent assessment of an application.

The IRB member shall disclose the conflict of interest at the following time(s):
1. When the IRB member is contacted to participate in the review of a project from a Principal Investigator with whom the IRB member has a conflict of interest.
2. Prior to the discussion at a convened meeting of a project for which the IRB member has a conflict of interest.
3. Immediately upon discovery of the conflict of interest if at other than the foregoing times.

The members of the IRB retain the right to question other IRB members regarding their potential conflicts of interest at the time of protocol submission, and bring discussions of such potential conflicts forward to the committee as a whole.

Principal Investigators and Research Advisors

Principal Investigators are responsible for completing the "Known Conflicts of Interest" section of the IWU IRB Proposal form. The information provided should include any known conflicts of interest of the Principal Investigator, the Research Advisor or anyone else involved in the research. Known conflicts of interest include but are not limited to having an equity interest in a company that is a sponsor of the research or owner of products being evaluated in the research; having a financial interest in a particular outcome of the research; or any other circumstance that might cause the Principal Investigator(s), Research Advisor or anyone else involved in the research to be unduly biased toward a particular outcome of the research. Conflicts of interest are not necessarily prohibitive, but they must be disclosed. If a conflict of interest is recognized, the research design must adequately protect human subjects and study integrity from bias.

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