



Western Illinois University Institutional Review Board

Policy and Procedure for Human Subjects Research

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Introduction

The Western Illinois University (WIU) Institutional Review Board for the Protection of Human Subjects (hereafter IRB) developed this guide to assist faculty, staff, administrators and student researchers in understanding their role in the function and responsibility of research integrity at WIU. This guide is intended to introduce the investigator to the IRB, clarify the human subjects research review process, and simplify the preparation and review of research protocols. This manual is believed to be in full compliance with all applicable federal, state and university regulations. This manual supersedes all previous versions. All forms referenced in this guide can be found at the Office of Sponsored Projects website http://www.wiu.edu/sponsored_projects/compliance/hs_human_subjects.php.

IRB Mission

The mission of the IRB is to protect the rights and welfare of human subjects participating in research. The IRB is responsible for reviewing and monitoring all research that involves the participation of human subjects to ensure that research investigators are supporting the institution's mission to engage in ethical conduct of scientific inquiry.

IRB Accountability

The IRB is organized in the Office of Sponsored Projects, under the Provost and Academic Vice President. The IRB acts according to policies set forth by the United States Department of Health and Human Services (DHHS) that relate to the ethical standards of research involving human subjects (45 CFR 46). Every five years, or as needed, the IRB files a federal wide assurance with the Office of Human Research Protection (OHRP) that ensures that WIU is adhering to the federal guidelines as outlined by DHHS. Compliance with these federal regulations not only safeguards human subjects and the institution sponsoring the research project, but also protects the researcher.

IRB Appointment

The membership of the IRB, appointed by the Provost, is composed of members representing WIU faculty, staff and administrators, and community representatives. The Chair is an experienced faculty member, appointed by and responsible to the Provost. The committee makes an effort to preserve diversity by appointing scientists, nonscientists, and representation from various areas of expertise. The committee makes an effort to safeguard research integrity by staying current with applicable laws and regulations and applying knowledge of special populations such as children, prisoners, pregnant women, persons with disabilities, economically or educationally disadvantaged persons, or any other population that may be relatively or absolutely incapable or protecting their interests through the informed consent process.

IRB Guidelines

The IRB recognizes the following definition of *risk*, as defined by the Office of Health and Human Services:

“A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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.”

The IRB review shall determine whether or not human subjects will be placed at risk, and if risk is involved, whether or not:

1. Risks to subjects are outweighed by the sum of the anticipated benefits to the subjects and the importance of the knowledge that is expected to result from the research;
2. Risks to subjects are minimized by using procedures consistent with sound research design and ethical procedures;
3. Informed consent from each prospective subject will be legally sought and obtained in accordance with the federal policy for the protection of human subjects; and
4. Additional safeguards have been included to protect the rights and welfare of vulnerable populations (e.g., children, prisoners, persons with disabilities, pregnant women) who are necessary to the purpose and setting of the research.

The IRB recognizes the following definition of *research*, as defined by the Office of Health and Human Services:

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

The IRB recognizes the following definition of *human subject*, as defined by the Office of Health and Human Services:

“Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.”

A research protocol **MUST** be reviewed by the IRB under these guidelines if it meets all three of the following criteria:

1. it involves human beings as subjects;
2. it is research as defined above; and
3. the intention to publish or disseminate results **OR** the **POSSIBILITY** of publishing or disseminating results exists.

Any research that involves human subjects, whether funded or not, that is undertaken by a WIU faculty, academic staff or student or supported by Western Illinois University, must be reviewed by the IRB. Approval must be granted by the IRB prior to collecting data from any human subjects for research purposes or soliciting subjects for a research study.

IRB Authority

The WIU IRB certifies human subject research at the following three review levels:

- Exempt Review - To qualify, research must fall into one of six federally-defined exempt categories. These categories present the lowest amount of risk to potential subjects because they involve either collection of anonymous or publicly-available data, or conduct of the least potentially-harmful research experiments.
- Expedited Review - To qualify for an expedited review, research must fall into one of nine federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects.
- Full Review - All projects that do not fall into either the exempt or expedited review categories, or deal with special concerns or vulnerable populations go to the full IRB for review.

Responsible Conduct of Research

It is the responsibility of all faculty, staff, and student researchers that engage in research to preserve the integrity of science. It is the policy of Western Illinois University that all individuals engaged in research involving human participants must complete educational training, prior to initiation of a research project. Please see [page 12](#) for more information regarding human subjects in research training.

Noncompliance

Noncompliance means significant failure by an investigator to abide by University policy and relevant government regulations for protecting human subjects in research. Instances of noncompliance would include, but are not limited to beginning research before securing IRB approval, misuse or non-use of approved consent forms, failure to secure IRB approval before introducing changes in an on-going protocol, and continuing to gather study data from subjects after IRB approval expires.

Engaging in human subject research without or differing from an IRB approved protocol has serious ethical implications. Students, faculty, and staff are required to submit IRB protocols and follow the approved protocol when embarking on any data collection. Even pilot studies must be approved by the IRB.

Ramifications for Students:

- Credit may be withheld: Western Illinois University may refuse to grant students course credit for research conducted without IRB approval.

- Thesis work may not be accepted.
- Degrees may not be awarded for work based on projects which violate IRB protocol.
- Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication.
- Funding may be withheld: IRB approval is required if you are a participant in a grant program. These programs will not release funds without IRB approval. Funding may be required to be returned if it is determined that violations of approval has occurred.

Ramifications for Faculty and Staff:

- Funding may be withheld: Federal sponsors, and virtually all private sponsors, require IRB approval as a condition of funding. Sponsors may postpone review of proposals for which IRB review is not complete or pending at the time of proposal submission.
- Many sponsors will not release funds to the University for the investigator's use without IRB approval.
- Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication. Retractions may be required pending an investigation of non-compliance with approved protocols.
- Liability issues arising from unapproved research may become the responsibility of the investigator. Persons conducting unapproved research are deemed to be acting outside the scope of authority granted to them by the University.
- Suspension of research: The University may suspend all research activities for an indefinite time frame as a disciplinary measure or may require the mandatory destruction of all research data collected during a project.
- Other disciplinary action in accordance with University policy.

Exempt Research

The exempt process is much less rigorous than an expedited or full IRB review. To qualify, research must fall into one of six federally-defined exempt categories. Research activities that fall under any of the federally defined exempt categories may not be subject to IRB requirements (e.g., annual reviews, informed consent requirements). However, it is strongly suggested that informed consent always be used.

These categories present the lowest amount of risk to potential subjects because they involve either collection of anonymous or publicly-available data, or conduct of the least potentially-harmful research experiments. Private identifiable information **cannot** be recorded by the investigator or members of the research team if there is a possibility that release of that information could affect the individual's reputation, employability, or financial status.

An exemption cannot be granted for research that uses the following subject populations:

- research involving prisoners;
- some research involving children; Please see exemption 2 on the next page.)

Only the IRB Administrator is authorized to determine which protocols may be subject to limited review or may be exempt from review by the IRB. Investigators who believe that their research meets the following criteria may request exempt status for their study. The IRB reserves the authority to require proposal modifications regarding human subject protection before approving the research as exempt.

It is WIU's institutional policy, that once reviewed as exempt, a protocol does not need to be resubmitted for review, *unless* there have been changes to the protocol. Investigators believing their research activities to be exempt need to fill out the exempt review forms located at the following website: http://www.wiu.edu/sponsored_projects/compliance/hs_human_subjects.php. All forms should be submitted to the IRB Administrator in the Office of Sponsored Projects for review and approval. Student research requires that there is a faculty sponsor advising the study, thus faculty sponsor information must also be included in the form.

EXEMPT CATEGORIES – *WIU policy requires that an exemption determination be made by the IRB Administrator and may not be an independent determination made by an investigator.*

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

- (i) research on regular and special education instructional strategies, or
- (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (*Note: This exemption is applicable to individuals who are mentally disabled only if research involved no change in the content, location, or procedures of instruction from those normally experienced by the subject. This category may include children.*)

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the following two conditions exist:

- (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- (ii) 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.

When research in this category involves children, this exemption must be limited to the following activities:

- *Educational tests (cognitive, diagnostic, aptitude achievement)*
- *Observation of public behavior where the investigator(s) do not participate in the activities being observed.*
- *Note: Research with children that involves survey or interview procedures, or observation of public behavior where the investigator(s) participate in the activity being observed cannot be granted exemption.*

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 the category 2 above if:

- (i) the human subjects are elected or appointed public officials or candidates for public office; or
- (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Coding of records, statistical techniques, and physical or computerized methods for maintaining the security of stored data are among that available methods for ensuring confidentiality.

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. If a link exists anywhere including, but not limited to the source material, this study will not qualify for exemption, but may qualify for expedited review.

- *To qualify for this exemption, the data, documents, records or specimens must be in existence before the project begins.*
- *Under this exemption, an investigator may inspect identifiable records, but may only record information in a non-identifiable manner.*

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

- (i) Public benefit or service programs;
- (ii) procedures for obtaining benefits or services under those programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) 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,

- (i) if wholesome foods without additives are consumed or
- (ii) 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 FDA or approved by the EPA or [USDA Food Safety].

Expedited Research

Expedited review as defined by federal regulations allows the IRB Chair or the IRB Administrator to evaluate and approve research that put human subjects at minimal risk or less. Reviewers conducting an expedited review may exercise all of the authority of the IRB except

that they may not disapprove a study. When an IRB Chair or Administrator cannot approve the research under expedited review, the study is referred to the full IRB for review.

To qualify for expedited review, a research procedure must be limited to the activities that are federally approved for expedited review and incur no more than *minimal risk* for participant, or be a minor change in previously approved research that involves *no additional risk* to the research subject.

The activities detailed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion 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 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 standard requirements for informed consent apply regardless of the type of review. The expedited review procedure may not be used for classified research involving human subjects. The categories in this list apply regardless of the age of subjects, except as noted. Categories 1 – 7 pertain to both initial and continued IRB review.

To apply for expedited review, investigators complete either the Expedited Form for initial research review or the Review and Monitoring Form for continued research review. Both forms can be located at: http://www.wiu.edu/sponsored_projects/compliance/hs_human_subjects.php.

To qualify for an expedited review, research must fall into one of nine federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects. Some examples of expedited research are:

EXPEDITED CATEGORIES - *Research involving only minimal risk procedures as identified in the regulations, outlined below, may qualify for expedited review by the IRB Administrator.*

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. (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. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

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

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

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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. 45 CFR 46.101(b)(4). 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. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the 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.

Full IRB Review

A project that involves greater than minimal risk requires approval by the IRB. Research that requires full Board review can include:

- research that involves greater than minimal risk
- non-exempt research that involves children or other vulnerable populations
- research that involves experimental drugs or devices
- research that involves invasive procedures

Survey research that involves sensitive questions or information about sexual practice or illegal behavior is subject to full review, in keeping with federal guidelines. Any survey or interview that is likely to be stressful for the subject requires full Board review. The IRB Administrator will make this determination.

Research Personnel

All individuals who will interact or intervene with human subjects or their private, identifiable information must be included on the IRB protocol. If new members are added to the research team after IRB approval, the Principal Investigator must submit the WIU Review and Monitoring Form to notify the IRB of the additional personnel.

A student investigator cannot be listed as the Principal Investigator/Faculty Advisor on the protocol. The Principal Investigator/Faculty Advisor on the project must be a faculty or staff member at WIU. This individual is responsible for the conduct of all research personnel.

The IRB encourages faculty to work with students in their research endeavors. However, faculty are not permitted to require their enrolled students to serve as research assistants/investigators (including data collection) in the faculty's personal research. Recognizing that a potential for coercion exists when a faculty member requires a subordinate (e.g., enrolled student) to engage in a research study, the WIU IRB will not approve proposed research in which faculty require their students (over whom they have, or they can reasonably anticipate having, a supervisory role) to serve as research assistants/investigators for their own personal gain.

Recruitment of Students as Research Participants

The federal regulations do not specifically mention the inclusion of students in research, but their designation as a special population stems from 45 CFR 46.111(b):

“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.”

This regulation does not prohibit the inclusion of students in research, or provide specific criteria for inclusion. This guidance emphasizes the need for carefully considering whether the inclusion of students can be justified since the investigator's relationship with students is potentially coercive. Recognizing that a potential for coercion exists when a faculty member recruits a subordinate to participate in a research study, the WIU IRB routinely does not approve proposed research in which investigators will enroll students over whom they have, or they can reasonably anticipate having, a supervisory role. The IRB will consider the inclusion of students in research if the investigator has proposed adequate methods and guidelines for recruitment and participation to minimize coercive elements and risks to privacy and confidentiality. As a rule, the IRB disapproves of recruiting students as a targeted population, merely for the sake of convenience or because of their easy availability.

Research Conducted in Courses

Some research conducted in courses as a means of contributing to the students' individual knowledge and training in a particular academic discipline do not require Institutional Review Board (IRB) approval. Specifically, if the project is not intended to contribute to advances in generalizable knowledge, nor are the results of such activities to be published, presented, or archived, then the research does not need IRB approval. Unless the project places participants at

more than minimal risk, the project is not research subject to IRB review. Under this policy, minimal risk is seen in one or more of the following situations:

- Subjects are members of a vulnerable population (e.g., prisoners, minors under the age of 18, mentally or physically challenged individuals, people with diminished capacity to give consent).
- The study asks subjects about illegal activities (e.g., underage drinking), which may place the data at risk of subpoena.
- The study places subjects at risk of a breach of confidentiality that may lead to criminal or civil liability, or damage the subject's financial standing, employability, or reputation.
- The study places subjects at more than minimal risk due to psychologically sensitive subject matter (e.g., interviews covering traumatic events, information relating to sexual attitudes, preferences, or practices, information relating to an individual's psychological well-being or mental health).

Faculty are advised to discuss protection of human subjects with students before the instructional assignment or project begins so that informed decisions can be made about whether IRB review is needed. If even the slimmest likelihood exists that an instructional assignment or project may fall under the definition of research outlined in this document, students should submit a human subjects research protocol to the IRB for review and approval. Please note that IRB approval of a research protocol cannot be granted retroactively.

The course instructor is responsible for communicating to students the ethics of human subjects research, for ensuring the protection of human subjects (including having a process in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students' progress. Research collected in courses should be recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects. Instructors and students should be aware of the following:

- the elements of informed consent
- appropriate strategies for recruiting subjects
- identification and minimization of potential risks to subjects
- assessment of the risk-benefit ratio
- guidelines for protecting confidentiality and
- the IRB review process

Independent study projects, senior theses, undergraduate research projects, master's research, and similar exercises must be independently submitted for IRB review. It is important to keep in mind that any human subjects research activity that will ultimately contribute to part or all of a thesis, or other type of publication or presentation, must go through the IRB review process prior to enrolling subjects and collecting data. IRB review cannot occur after a study has begun.

Research Conducted or Affiliated with Outside Entities

WIU researchers who participate in off-campus research must receive approval from the WIU IRB *and from* the IRBs at any outside institutions participating in or sponsoring the research. If no IRB or IRB-like committee exists at a given institution, researchers should consult the WIU IRB on how to document the outside institution's approval. Researchers might be required to provide formal, written assurance that the research will be conducted according to ethical standards. The WIU's approval of off-campus research is made contingent on outside institutions' approvals and assurances.

Off-campus research at sites that are not formally affiliated with an institution, government, or other agency (*e.g.*, in foreign countries or remote locations) must still receive approval from the WIU IRB. The research must be approved by the local equivalent of an IRB for the off-campus site or, where there is no equivalent group, by local experts or community leaders. Appropriate permissions must be documented.

Procedures for Submitting Protocols

1.) Complete the Human Subjects in Research Training –

Undergraduate Class Project:

Before students engage in research that involves human subjects at Western Illinois University they must complete the mandatory Collaborative Institutional Training Initiative (CITI) modules. Please see the following page for the directions:
http://www.wiu.edu/sponsored_projects/compliance/hs_training.php.

Upon completion of this training, the students will be able to print out a “Completion Certificate”. This certificate must be included as part of the protocol or on file in the Office of Sponsored Projects to be reviewed by the IRB. No protocol will be approved without this certification.

Note: As an alternative to the CITI training, students can complete the NIH training modules: <http://phrp.nihtraining.com/users/login.php>.

Faculty, Graduate Students, Research Assistants, or Research Investigators:

Before researchers engage in research that involves human subjects at Western Illinois University they must complete the mandatory National Institute of Health modules. Please navigate to the following link for training: <http://phrp.nihtraining.com/users/login.php>.

Upon completion of this training, the researchers will be able to print out a “Completion Certificate”. This certificate must be included as part of the protocol or on file in the Office of Sponsored Projects to be reviewed by the IRB. No protocol will be approved without this certificate accompanying the protocol or on file in the Office of Sponsored Projects.

Note: As an alternative to the NIH training, researchers can complete the *Social and Behavioral Research* CITI training modules: <http://www.citiprogram.org>. The CITI modules provide the necessary requirements for human subjects training, however they take more time to complete than the NIH training.

2.) Complete the appropriate protocol form, including all necessary materials for IRB review. All forms are available on the Office of Sponsored Projects website: http://www.wiu.edu/sponsored_projects/compliance/hs_human_subjects.php. Complete protocols should be submitted to:

Jacqueline Tharpe
Compliance Specialist
1 University Circle, 320 Sherman Hall
Macomb, IL 61455-1390

3.) While department or college level reviews are not required, researchers are strongly encouraged to have their protocols checked by colleagues, faculty mentors, or the IRB Administrator prior to submission.

Note: Adequate time is a necessity for the IRB to review protocols. **A full IRB review may take several months to complete. Protocols must be received in the Office of Sponsored Projects at least two weeks prior to the next scheduled meeting.**

Specific Requirements

1. IRB protocol forms need to include all required information and appropriate signatures.
2. A copy of all materials needs to be included with your protocol submission. Including, when applicable, the informed consent, child assent document, parental consent documents, a copy of the survey instrument/questionnaire, and a cover letter, if utilized.
3. A copy of any supporting material/appendices that the investigator believes necessary (letters of agreement, support or requests) for a thorough review of the proposed research protocol.
4. Human Subjects in Research Training certification must be included as part of the protocol or on file in the Office of Sponsored Projects to be reviewed by the IRB.
5. Research conducted in cooperation with other agencies or organizations, e.g., University of Illinois, Illinois State University, Bridgeway, etc., may require review by those organizations' IRBs and a letter of approval from the WIU IRB.

Informed Consent Guidelines

Obtaining the informed consent of a potential human subject for participation in any research (whether an experiment, survey, interview, or demonstration) is a federally mandated safeguard for protecting the rights and welfare of all individual subjects, and, in fact, constitutes the very essence of protecting those rights. Therefore, the IRB will very carefully review the method of obtaining and the content of informed consent listed below. When consent forms require signatures of research subjects and/or their parents or legal guardians, a copy of the fully signed

form must be given to the subject/parent/guardian and **a copy must be retained by the researcher for a minimum of three years after completion of the project.** The consent form should avoid jargon and should be presented in lay persons' language, and appropriate to the "audience." An informed consent document template can be found on page 17. Be sure to adapt it to your specific project.

The consent form, headed with the title of the project, needs to include the following information:

1. Statement that the study involves research (if disguised or deceptive procedures are used, a debriefing plan must be explained to the IRB).
2. Explanation of the purposes of the research (including the extent to publish, present or disseminate information).
3. Expected duration of the subject's participation in the research and where testing will take place.
4. Description of the procedures to be followed.
5. Identification of any procedures that are experimental.
6. Description of any reasonably foreseeable risks or discomforts to the subject and what will be done to address these, if present.
7. Description of any benefits to the subject or to others that may reasonably be expected from the research.
8. Disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject in making an informed decision whether or not to participate in the research (this pertains primarily to medical research and drug trials).
9. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and a description of the measures to be taken to insure anonymity of individual subjects.
10. For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs, whether any medical treatments are available if injury occurs, and if so, what they consist of or where further information can be obtained.
11. Explanation of whom to contact for answers to pertinent questions about the research (student investigators are required to include the name, address, and phone number of his/her faculty research advisor), research subject's rights, and whom to contact in the event of a research-related injury to the subject.

It is suggested that the following statement is included in every consent form, "This project has been reviewed and approved by the WIU Institutional Review Board. Questions concerning your rights as a participant in this research may be directed to Jacqueline Tharpe, Compliance Specialist, at (309) 298-1191 or IRB@wiu.edu."

12. Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
13. The consent form needs spaces for the signatures and dates for both the investigator and the human subject.

Please note the following:

If the subjects are minors under the age of 18, an assent document must be used and the consent signatures of a parent or guardian and assent signature of the minor must be obtained.

The consent form cannot include a statement releasing the investigator, sponsor, institution or its agents from liability or negligence.

Informed Consent Document Template **[Project Title]**

Purpose:

You are being asked to participate in a research study about *[insert general statement about study]*. The purpose of this research is *[insert a statement of purpose]*. You were selected as a possible participant because *[explain how participant was identified]*. Please read this form and ask any questions that you may have before agreeing to be in the research.

Information about Participants' Involvement in the Study:

The study will take place in *[building and room]*. It should take you approximately *[state the amount of time required of participants per session and for the total duration of the research]* to complete the research study.

If you agree to be a participant in this research, we would ask you to do the following things: *[List all procedures, preferably in chronological order, which will be employed in the research. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using non-technical language. Explain all procedures using language that is appropriate for the expected reading level of the participants.]*.

Risks:

This research has the following risks: First, *[explain first risk, including the likelihood of the risk and any measures that will be used to minimize the risks]*. Second, *[explain second risk, including the likelihood of the risk and any measures that will be used to minimize the risks]*. *[Continue providing the risks, as necessary]*.

Benefits:

The benefits of participation are *[explain benefits of participation that will be gained, either by the participants, society, or to the body of knowledge (Note: monetary compensation is not considered a benefit of being in the study)]*.

Compensation:

You will receive the following payment/reimbursement: *[Explain the amount of payment or other reimbursement information (i.e., class credits), as well as when payment and/or reimbursement will occur. If applicable, indicate other ways participants can earn the same amount of credit or compensation]*.

Confidentiality:

The information in this research will be kept confidential. *[State how the data will be coded]*. Research data will be stored in a secure location. *[State why the location is secure. (e.g., locked filing cabinet/room with limited access)]*. The data will be made available only to the persons conducting the research. No reference will be made in oral or written reports that could link participants to the research. *[If tape or video recordings are made, explain who will have access to them, and when they will be erased/destroyed]*.

Voluntary Participation:

You do not have to perform any activity you do not want to. You do not have to answer any question you do not want to answer. Participation in this study is voluntary. If you decide to

participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled.

Contact Information:

If there are any questions at any time about the study or the procedures, or you experience adverse effects as a result of participating in this study, please contact:

Faculty Member Name
Department
Western Illinois University
Telephone Number
E-mail Address

Student Name
Telephone Number
E-mail Address

This project has been reviewed and approved by the WIU Institutional Review Board. Questions concerning your rights as a participant in this research may be directed to Jacqueline Tharpe, Compliance Specialist at (309) 298-1191 or IRB@wiu.edu.

Consent:

I have read the above information, and I have received a copy of this form. I agree to participate in this study.

Participant's Printed Name	Signature	Date
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Investigator's Printed Name	Signature	Date
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Glossary of Terms

ANONYMITY - means that the identity of a subject is not identifiable with his or her responses.

ASSENT - Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research.

ASSURANCE - A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

BENEFIT - A valued or desired outcome; an advantage. (Note: monetary compensation is not considered a benefit of being in a study).

CHILDREN - Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted.

COGNITIVELY IMPAIRED - Having either a psychiatric disorder (*e.g.*, psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (*e.g.*, mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

COMPETENCE - Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

CONFIDENTIALITY - Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

CONTINUING REVIEW - If data gathering continues for more than twelve months, federal regulations require that the project be subject to a "continuing review." Researchers should use the WIU IRB Review and Monitoring form. This form is also to be used if changes in the research protocol occur within any given twelve-month period.

DATA COLLECTION - Refers to any research procedure that is intended to elicit from or record the actions, reactions, attitudes, and/or behavioral manifestations of subjects participating in a research project.

DEBRIEFING - Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

EXEMPT REVIEW – Research activities that fall under any of the following federally defined exempt categories will qualify for an exempt review, and may not be subject to IRB requirements (e.g., annual reviews, informed consent requirements). To qualify, research must fall into one of six federally-defined exempt categories (see page 7).

EXPEDITED REVIEW - Review of proposed research by the IRB Administrator rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research (see page 9).

FULL BOARD REVIEW - Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting (see page 11).

GUARDIAN - An individual who is authorized under applicable state or local law to give permission on behalf of a child or cognitively impaired individual to general medical care.

HUMAN SUBJECTS - Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

INFORMED CONSENT - A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

INSTITUTIONAL REVIEW BOARD - A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

MINIMAL RISK - A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

MONITORING - The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

NONAFFILIATED MEMBER - Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., minister, business person, attorney, teacher, homemaker).

PERMISSION - The agreement of parent(s) or guardian to the participation of their child or ward in research.

PRINCIPAL INVESTIGATOR - The scientist or scholar with primary responsibility for the design and conduct of a research project.

PRISONER - An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (*e.g.*, for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

PRIVACY - Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

PROTOCOL - The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support.

RESEARCH - A systematic investigation (*i.e.*, the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

RISK - The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

VOLUNTARY - Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

VULNERABLE POPULATIONS - Refers to subjects such as children, prisoners, pregnant women, persons with disabilities, economically or educationally disadvantaged persons, or any other population that may be relatively or absolutely incapable or protecting their interests through the informed consent process.