

Institutional Review Board Policies and Procedures (Faculty Handbook Chapter VI F, sections 1 & 2)

F. Policy Statements on Research

1. INSTITUTIONAL REVIEW BOARD: AUTHORITY, COMPOSITION, LEVELS AND REVIEW PROCEDURES

Authority of the IRB

The IRB is responsible for reviewing and monitoring research involving human subjects conducted by faculty, students, and investigators seeking access to students, staff and/or faculty under the auspices of the University. It has the authority to prohibit research that does not meet the standards of ethical research practices. It also has the authority to suspend or terminate approval of research that is not being conducted according to these standards.

All research which involves human subjects must be reviewed by the IRB. Approval is necessary prior to initiation of the project. Continuing research projects are subject to annual review. The IRB may monitor research at intervals appropriate to the degree of risk to study subjects.

The IRB has the authority to take one of four actions. Research may be approved, approved conditionally, disapproved, or be granted exempt status. In order for research to be approved it must meet the standards of ethical research practices.

The IRB shall notify investigators in writing of actions taken regarding proposed research and maintain full records in the Office of the Associate Provost regarding its activities. If approval is conditional, the investigators must respond to the conditions set forth by the IRB prior to conducting the study. If the IRB disapproves a research project, it must include reasons for its decision in its written notification. Investigators may address these reasons and resubmit the proposed research project for further consideration.

The IRB may request information on any aspect of a proposed study. As part of the review process, the IRB may request supplementary information, demonstration of the procedures to be used and/or regular progress reports. The IRB has the authority to observe or to have a third party observe any aspect of the research project, including methods used to obtain consent from study subjects. It may also seek the advice of consultants. Any unforeseen complications or adverse reactions to approved research must be immediately reported to the IRB.

Composition of the IRB

The Institutional Review Board shall consist of at least seven members. The Associate Provost will recommend appointees to the Nominating Committee and appointments will be approved by the President. Members of the IRB will include individuals who have expertise in diverse aspects of human subject research. They shall be able to ascertain the acceptability of proposed research in terms of

institutional commitments and regulations, applicable laws, and standards of professional conduct and practice. In particular, the following requirements shall be met: 1) The IRB may not consist entirely of members from one academic discipline or profession. It must include both men and women. 2) At least one member of the IRB shall be a person whose primary expertise or concerns are in a scientific area and one in a nonscientific area. 3) At least one member of the IRB shall be a person who is not affiliated with the institution or who is not part of the immediate family of a person who is affiliated with the institution. 4) The IRB may invite individuals with special competence in a research area to aid in the review process. 5) Members of the IRB are prohibited from participating in the review of research proposals if there is any conflict of interest.

Levels of IRB Review

There are three levels of review: Exempt, Expedited, and Full.

Note: **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(A) Categories of Research Qualifying for Exempt Status

Exemption from the requirement for IRB approval is granted when it is determined that the project does not constitute research as defined by *Federal Policy for the Protection of Human Subjects* and the IWU Institutional Review Board or if the research meets one of six specific exemption categories.

Note that the IWU IRB has made the following interpretations of its charge:

The ultimate decision of whether an activity is or is not research rests with the IRB. Any activities that might conceivably be construed as research require IRB approval as “exempt”. This process is designed to be as streamlined as possible and applicants should submit the form requesting approval of the research as “exempt” by filing a hard copy of this application in the office of the Associate Provost and an e-mail copy to the IRB.

IWU considers that both qualitative and quantitative methodologies may constitute research. Thus, attempts to obtain information using such methodologies as focus groups, interviews, participant observation, etc. require approval.

Research-like activities that are conducted solely by members of a class are typically not defined as research, although instructors need to ensure that these

activities do not violate the rights of participants. Activities in which class members collect data from members of the larger IWU community or from persons in the community constitute research and are subject to the review of the IRB.

Research that meets one the following six specific categories can fall under the exempt category.

Most educational research, test design research, anonymous surveys and interviews, observations of public behavior, and many kinds of program evaluation will qualify for exempt status. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be considered to present minimal or no risk to research subjects and may qualify for exempt status. The categories are:

- (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.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (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.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, 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.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(B) Categories of Research Qualifying for Expedited Review

The IRB may use an Expedited Review Process to review research that involves only minimal risk to subjects or consists of minor changes to previously approved research during the period (one year or less) for which approval is authorized. Minimal risk is defined as activities in which the probability and magnitude of harm or discomfort anticipated in the research is no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(C) Full Review

Research that does not qualify for Exempt or Expedited Review will fall under the category of Full Review.

Review Procedures

The IRB shall meet at least bimonthly during the academic year and may meet as often as necessary. At least one member whose primary concerns are in a scientific area and one member whose primary concerns are in a nonscientific area must be present. Individuals invited to contribute to the review process do not have a vote. Proposed research must be approved by a majority of those members present. Disapproval may not be overruled by any other University group or official.

Reviews of exempt protocols and reviews of extensions and/or minor changes to previously approved studies may be carried out by the IRB chair or by one or more experienced reviewers designated by the IRB chair from among members of the IRB. Expedited proposals will be reviewed by two IRB members. In reviewing the research, the reviewers may exercise all the authority of the IRB except that the reviewers may not disapprove of the proposed study. All members of the IRB will be advised of research proposals which have been approved under

either of these review procedures.

The IRB shall make a report of its proceedings to the Office of the Associate Provost which will also serve to maintain these records as appropriate.

2. POLICIES REGARDING USE OF HUMAN SUBJECTS IN RESEARCH AT ILLINOIS WESLEYAN UNIVERSITY

Overview

While Illinois Wesleyan University recognizes the need for and value of research involving human subjects, it also recognizes its responsibility for ensuring that the privacy, safety, health, and welfare of human study subjects are adequately protected. All research involving human subjects conducted under the auspices of Illinois Wesleyan University is expected to meet general standards of ethical research practices established by Federal Regulations (FR Doc 91-14257) and the standards of specific professional organizations (i.e., the American Psychological Association, American Nurses Association, American Sociological Association and the World Health Organization.)

An Institutional Review Board (IRB) has been appointed to ensure that the basic rights and welfare of human subjects are safeguarded, that methods used to obtain consent from research subjects are appropriate, and that any risks to study subjects are acceptable and are always minimized. Risks exist when subjects may be exposed to possible physical, psychological or other harm.

All research involving human subjects conducted under the auspices of Illinois Wesleyan University must be reviewed by the IRB. Approval is necessary prior to the initiation of any such project. Continuing research projects must be renewed annually.

Information for investigators regarding research guidelines, criteria of approval and appropriate procedures for review of proposed research is described in Information for Investigators Using Human Subjects. Faculty supervising student research as part of course work are directed to the section identified as Student Research, which will be found under Information for Investigators Using Human Subjects, Information describing the functioning of the IRB is described in Institutional Review Board Authority, Composition and review Procedures.

Information For Investigators Using Human Subjects

All research involving human subjects conducted under the auspices of Illinois Wesleyan University must be reviewed by the IRB. This includes research projects initiated by students, faculty or staff at IWU. It also includes projects conducted by investigators not affiliated with the institution which use Wesleyan students, faculty or staff in virtue of their affiliation with the University. The IRB is also responsible for reviewing research involving human subjects that is conducted by IWU faculty, staff, or students at other locations. IWU IRB review is required even if an IRB review is completed at these other sites. Approval from

the IRB is necessary prior to initiation of any research. Continuing research projects are subject to review on an annual basis. The IRB will monitor research projects at intervals appropriate to the degree of risk to study subjects.

The IRB has the authority to take one of four actions in regard to research involving human subjects. The research may be deemed exempt, approved, approved conditionally, or disapproved. During review, the IRB may also request additional information regarding the proposed research. When conditional approval is granted, the specified conditions must be met and approved by the IRB before the investigator initiates the project. If the IRB disapproves a research project, it must include in its written notification the reasons for its decision. Investigators may address these reasons and resubmit the proposed research project for further consideration.

(A) Standards of Ethical Research Practice

In order for research to be approved or to be exempted, it must meet the following standards of ethical research practice:

- (1) The rights of the subject must always take precedence over the interests of society, the interests of the investigators or the value of the research. Research which violates the rights of study subjects will be prohibited. These rights include the following:
 - a. Subjects have the right to informed and voluntary consent or dissent. Informed consent must be appropriately documented. (Standards for Informed Consent are discussed in the following section.)
 - i. Information provided to gain subject consent must be adequate and relevant. All information which would reasonably be needed in order to make an informed decision must be provided in a manner that is understandable to the subject before consent is obtained. This includes being informed about any foreseeable risks.
 - ii. Participation of a human subject in any research project must be voluntary. Study subjects have the right to decide whether or not to participate in the research without coercion, undue influence, or duress. When some or all of the subjects are likely to be vulnerable to coercion or undue influence (i.e., students, children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these subjects.
 - iii. Study subjects have the right to decide not to participate in research or to withdraw from participation at any time without adversely affecting the relationship between the subject, the investigators, and the University. In those cases where participation in a research project is intended to provide an educational experience, potential participants must be informed

that they are not obliged to participate and that appropriate alternatives to participation will be provided.

- b. Subjects have the right to privacy and confidentiality. Appropriate safeguards must be provided to protect the privacy of subjects and to maintain the confidentiality of data gathered.
 - c. Subjects have the right to ask questions about the research at any time before, during and after participation in the research. These questions must be answered in an adequate and satisfactory manner.
 - d. Subjects have the right to be treated with dignity and respect at all times.
- (2) Research involving human subjects must be preceded by careful assessment of predictable risks to the subjects or others. Standard and scientifically recognized methods for assessing risks must be employed. Risk exists when subjects may be exposed to any possible physical, psychological, or other harm. Risks may result from procedures which cause discomfort or anxiety to study subjects or invade their privacy or pose threats to their dignity. Risks to human subjects must always be minimized (a) by using procedures consistent with sound research design and (b) whenever appropriate, by using accepted procedures already performed on subjects for diagnostic, treatment or other purposes.
 - (3) Research projects involving human subjects must be conducted or supervised by qualified persons.
 - (4) Selection of study subjects must be equitable.

(B) Informed Consent

Informed consent must be obtained in most studies that involve human subjects. Investigators should consult the *Federal Policy for the Protection of Human Subjects*, which is available in the Office of the Associate Provost, for the specific rules involving informed consent and the circumstances under which specific rules apply. Any explanation, whether in written or oral format, must be given in the language of the subject by a person competent in the area of the proposed research.

For each study, the principal investigator must submit a specific informed consent form. If only verbal consent will be obtained, a script of the oral explanation of the study must be submitted, along with a justification for not using a written form.

In most cases, consent forms should be written in the first person, and must include the following:

- (1) A title, descriptive of the study, in simple terms.
- (2) The date of preparation or revision.
- (3) A statement that the project is research, an explanation of the purpose of

the study, and the procedures to be followed.

- (4) Statement of the reason for the subject's selection, and the expected duration of the subject's participation.
- (5) A description of the potential benefits to the subject or others which may reasonably be expected.
- (6) A description of the reasonably foreseeable immediate and long-term discomforts, hazards, and risks and their potential consequences.
- (7) A statement that the investigator is available to answer any inquiries concerning the study, and information on who the principal investigator is and how to reach him/her.
- (8) Information regarding persons to contact in the event that any injuries or adverse consequences emerge from the research.
- (9) A statement that the research is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- (10) A statement that the subject may refuse to participate or withdraw from the study at any time without any negative consequences.
- (11) A statement that no information that identifies the subject will be released without separate consent except as specifically required by law. A statement outlining the extent to which records will be confidential.
- (12) A statement that if the use of the data is to be changed, the subject's consent will be re-obtained.
- (13) The name and telephone number of an IRB member to be contacted if participants have concerns about the ethical conduct of the study.
- (14) A signature and date line.

Special Circumstances Involving Informed Consent: Include in the consent form any of the following information that may be applicable:

- (1) If recordings are to be made, state this, and inform the subjects about the use of the recordings and what will happen to the recordings after the study.

Note that we will likely have separate informed consent protocols for filming and recording.

- (2) If the subject is a legal minor, a parent or guardian must sign the informed consent form. Suitably mature children should be provided with the opportunity to assent to participate in research. Depending upon the competency of the child, this may be administered either verbally or in written form. If the subject cannot sign, through disability or illiteracy, but is otherwise capable of being informed and giving verbal consent, a third party (not connected with the study), next of kin, or guardian shall witness the process, sign for the subject, and state the reason. When appropriate, detail the consequences of a subject's decision to withdraw from the

research.

(C) Initiating the Review Process

Investigators are required to submit Research Proposal Information (available in the Associate Provost's Office and on-line at <http://www.iwu.edu/irb/>). Some research which represents minimal risk to study subjects may qualify for exempt status. Note that exempt status is an outcome of the IRB review process. The investigator must review the information listed under Categories of Research Qualifying for Exempt Status to determine whether the proposed research may be placed in this category. Research presenting minimal risk to subjects may be submitted under the category of "Expedited Review."

To initiate the review process, investigators should submit one hard copy of all documents to the Office of the Associate Provost and one electronic copy to irb@iwu.edu. The schedule of IRB meetings will be available in the office of the Associate Provost and on-line at <http://www.iwu.edu/irb/>. Investigators should have materials requiring full review available at least two weeks prior to the next meeting date. Applications requesting expedited and exempt review can be submitted at any time. The IRB has the final authority to decide whether the research is appropriately considered under a review category other than the one selected by the applicant. To ensure the fastest turn-around time under that scenario, investigators seeking expedited review may wish to submit their materials two weeks prior to the next IRB meeting as well.

Investigators who wish to make any changes to a previously approved study must submit these proposed changes in writing through the Office of the Associate Provost to the IRB. The reviewing committee may request additional information if necessary.

(D) Student Research

To ensure that all student research comply with mandated requirements for the protection of human subjects, all research conducted by students that involve human subjects require IRB approval. The only exception is if students enrolled in the same class collect data from each other and results are presented only to members of that class.

Students may not submit protocols to the IRB; protocols can be submitted only by faculty or staff. While instructors might wish to provide students with the experience of writing IRB applications, instructors will need to review and modify these proposals prior to submission to the IRB to ensure that they fully address the requirements for human subjects research and that these are complete and well written. Instructors attest that student research meets the requirements of human subjects research and that they will oversee the students' efforts to ensure that they follow the protocol and respect the rights of research participants. Requiring faculty members to review and submit student research protocols will help IRB to perform its job more efficiently.

Most student projects can be grouped under one of the following categories.

(1) Group Protocol for a Class Project

In many instances, students work collectively on one research study. For example, students might construct surveys that they administer to students on campus, conduct ethnographic interviews with others on or off campus, conduct political opinion polls, or interview persons in various professions. It is possible for the instructor to submit a single protocol that provides a description of the parameters of the research activities provided that these research projects are low-risk, involve students in very similar research activities, and impact a similar sample of participants. The instructor is then responsible for monitoring the student research activities to ensure that all activities fall within the parameters of the approved group proposal and that the rights of the participants are respected. Note that if only slight variations in the research exist across different courses or across multiple courses, it is preferable for instructors to submit a single protocol that covers the range of activities across all of these courses.

(2) Umbrella Protocol Covering Multiple Student Projects

In some classes, instructors might have students design and complete individual projects that share common features. In this case, it is recommended that instructors prepare an umbrella proposal that addresses either the entire class or a subset of these projects. The instructor might prepare a general description of the project and one or more informed consent templates. Then, students could attach descriptions of each of their individual projects detailing their sample, specific assessment methods, and possible risks and benefits. The IRB will review this umbrella proposal and provide feedback to the instructor regarding any projects that are problematic. Under such circumstances, it will be the instructor's responsibility to work with individual students to clarify or modify their individual projects. Instructors will then be responsible for supervising the activities of the students to ensure that they conduct their research within the parameters of the approved umbrella protocol and that the rights of the participants are respected.

(3) Individual student projects

In some cases, students complete individual projects that require a separate protocol to the IRB. This is specifically pertinent for thesis and independent study projects. In this case, instructors will need to submit an individual protocol to the IRB.

(E) Responsibilities of Investigators to the IRB

Investigators must conduct the research within the parameters of their approved protocol.

Investigators may deviate from the approved project protocol only for the safety of the participant. The IRB must be notified as soon as possible and in writing of any deviation from the approved project protocol.

Investigators must notify the chairperson of the IRB as soon as possible and in writing of any adverse occurrence.

Investigators must supply an annual progress report to the IRB for projects extending beyond one year. However, the IRB may request additional progress reports and these must be supplied in a timely manner.

Investigators must submit a final overview of their research upon completion or termination of their projects. Projects which qualify for exempt status are not required to submit a final overview report.

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