



## **INSTITUTIONAL REVIEW BOARD MANUAL**

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# 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”) upholds the standards of U.S. government agencies (Code of Federal Regulations Title 45, Part 46). A copy of these standards can be found in the University Library, the Academic Affairs Office and divisional/departmental offices.

Using these 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, and students meets the standards required by governmental agencies, thereby protecting investigators and the institution.

**The Board’s only interest 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:** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Subject:** Any person studied in any research investigation and related activity.

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

**Research Supervisor:** A research supervisor 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 supervisor will ensure that the research will conform to the moral and ethical standards of Indiana Wesleyan University as well as comply with all Indiana Wesleyan University and Federal regulations regarding human rights. **A research supervisor shall be a faculty member of Indiana Wesleyan University.**

**No Risk:** No risk or injury to human subjects in any area of development and includes only:

- A. Observations of public behavior and use of public information.
- B. Anonymous data on human subjects.

**Minimal Risk:**

The observation of public behavior and collection of data that may be linked to the subject. The research is unlikely to produce harm to the human subject in any area of development.

**Moderate Risk:**

The research may produce (moderate, some) harm to the subject in his/her physical, mental, social, emotional, or spiritual state. The research may involve some deception of subjects that does not violate appropriate ethical codes or guidelines.

**Informed Consent:**

Informed consent means the knowing consent of an individual (or 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 purpose of project, procedures that will be used, length of project, anticipated risks and/or benefits, subject's right to terminate participation at any time, any cost or benefit to participant, and details regarding authorization for access to the subjects' personal records.

**All consent forms will contain the following statement:**

I will cooperate freely 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.

**Exempted Research:**

Exempted research is all research that in no way involves the use of human subjects. In addition, eleven categories listed in Section V. Scope of the manual are exempt from review if the subjects are eighteen years of age or older.

Academic division/department coordinators or their designees in cooperation with the principal investigators are empowered to determine whether a plan must be reviewed.

**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 ten categories listed in Section V. Scope of the manual. Expedited research is to be reviewed by the IRB chairperson plus one or two Board members.

**Full Review:**

Research that involves more than minimal risk or is not covered by the categories listed previously will require 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 full review. Research where there is risk to children requires full review. Full review requires review by all members of the Institutional Review Board.

### **III. STRUCTURE FUNCTION AND SCOPE**

The Code of Federal Regulations (Title 45, Part 46.107, IRB membership) guides the design of the Institutional Review Board. Board structure is drawn from the College of Arts & Sciences, College of Adult & Professional Studies, Wesley Seminary, School of Nursing, School of Health Sciences, and the Graduate School.

### **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. The Board will review proposals upon receipt and submit their review to the IRB office. **Approval will be granted by a two-thirds majority agreement of the Board.**

### **V. SCOPE**

#### **A. Research that is exempt from review**

Some types of research conducted by students and employees of Indiana Wesleyan University are exempted by the Board. Academic division/department coordinators or their designees are empowered to determine whether a plan must be reviewed. Applications do not have to be completed for projects which are exempt from review. However, documentation of exempt research plans must be submitted to the IRB office within a week of the determination that the project is exempt. The Board is prepared to provide advice and assistance to investigators whose projects are exempt.

All research that in no way involves the use of human subjects is exempted from review. In addition, the following categories of research are exempt from review **if the subjects are eighteen years of age or older:**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special education instructional strategies or (b) research on the effectiveness of or the comparison of instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude and/or achievement), survey procedures, interview procedures or observation of public behavior if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects which would place the subjects at risk of criminal or civil liability or damage 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 (including observation by participants) of public behavior, that is not exempt under (2) of this section if: (a) the subjects are elected or appointed public officials or candidates for public office or (b) 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 designed to study, evaluate, or otherwise examine: a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; or (c) 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 good is consumed that contains a good 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.

#### **Subjects Less than Eighteen Years of Age**

Federal regulations also allow some exemptions for research projects involving subjects less than eighteen years of age. As with adult subjects, the division/department chair in cooperation with the principal investigator is allowed to decide if the project is exempt. The Board wishes to emphasize its special concern for research projects using minors. Investigators with questions are urged to contact the committee chair concerning the exemption requirements or research projects using minors as subjects. The Board will provide additional information or counsel to enable the principal investigator to properly utilize these exemption categories.

The following categories of research are exempt from review **if subjects are less than eighteen years of age**.

7. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special education instructional strategies or (b) research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.
8. Research involving the use of educational tests (cognitive, diagnostic, aptitude and/or achievement) if information taken from these sources is recorded in such a manner that subject cannot be identified directly or through identifiers linked to the subjects.
9. Research involving observation of public behavior where the following conditions exist: (a) observations are recorded in such a manner that the institution cannot be identified, directly or through identifiers linked to the subjects, (b) the observations recorded about the individual, if they become known outside the research, **would not** reasonably place the subjects at risk of criminal or civil liability **or** be damaging to the subject's financial standing or employability, (c) the research **does not** deal with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol and (d) the investigator(s) **does not** participate in the activities being observed.
10. 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.
11. Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of the U.S. Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (a) programs under the Social Security Act, (b) procedures for obtaining benefits or services under those programs or (c) possible changes in methods or levels of payment for benefit or services under those programs.

#### **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 health 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 approval of the full Board (full review)**

Research, which involves more than minimal risk or is not covered by the categories listed previously, will require 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 full review. Research where there is risk to children requires full review.

### **VI. PERMISSIONS**

Any research which involves the use of Indiana Wesleyan University students, staff, or faculty will require the appropriate permissions to be granted. Permissions can be sought from the appropriate academic unit leadership and will be kept on file with the IRB at IWU.

### **PLEASE NOTE:**

A **complete proposal** as defined in this document is necessary for all non-exempt research. Submittal of a proposal does not require a Board meeting. Approval can usually be granted within a week to ten days of receipt of the application.

(The above was in large measure taken from "Instructions for Applying for Permission to Use Institutional Research", Board of the Use of Human Research Subjects, Purdue University (1994). That document in turn drew heavily from language in the Code of Federal Regulations, Title 45, Public Welfare, Part 46—Protection of Human Subjects as revised June 18, 1991.)

Appreciation is also expressed to Biola University, La Mirada, CA, for sharing their documents.



## INSTITUTIONAL REVIEW BOARD

### GUIDELINES FOR THE PREPARATION OF A PROPOSAL

A proposal is a WRITTEN STATEMENT, SIGNED BY THE PRINCIPAL INVESTIGATOR AND ADVISOR (if applicable), which conforms to provisions 1 through 15 below.

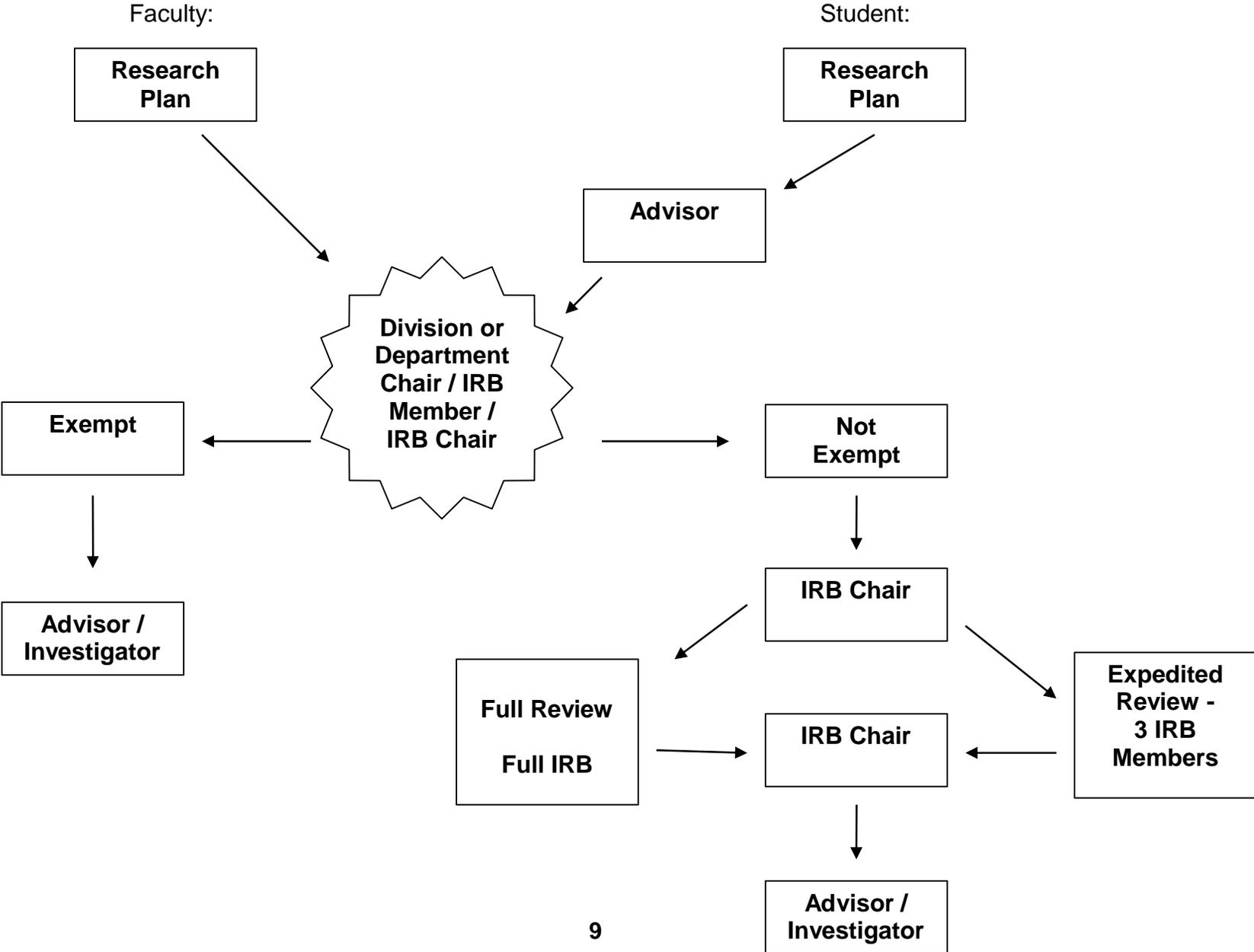
The proposal, as approved by the Institutional Review Board, becomes part of the agreement between Indiana Wesleyan University and the investigators about the way in which a project will be conducted. Therefore, the protocol must be an accurate description of the research project. The protocol, informed consent documents and other supporting materials become part of the public record of the IRB's deliberations. Any change in the approved protocol, including supporting documents, must be approved by the IRB. In order to ensure the integrity of the research study, the protocol will not be available for review by the public until the research project is completed.

A protocol, in writing and suitably titled or identified, must contain the following information (Please do not include the text of steps 1-16 in your proposal):

1. Include the IRB Proposal Checklist.
2. A title page which conforms to the format.
3. A summary of the nature and purpose of the research.
4. A full description of the human subjects involved, their characteristics, the total number anticipated and how they will be selected. Indicate explicitly whether any subjects are minors (under age 18) or are otherwise members of "vulnerable" populations (e.g. prisoners, hospital patients, or inpatients in state hospitals, such as the mentally infirm or disabled, or others whose ability or competence to give voluntary informed consent may be questioned). Populations subject to "undue influence" (e.g. college classes, interest groups, clubs, Sunday School classes, and /or Bible study groups) should be considered "vulnerable". The reason for using minors or members of "vulnerable" populations as subjects should be stated clearly.
5. A full description of exactly how the subjects will be used in the research.
6. A full description and assessment of the potential benefits, if any, to the individual human subject, and /or to the group or class of which the subject is a member, and/or to society in general as a result of the research.
7. A description and assessment of the potential risks, if any, to the individual human subject, and/or the group or class of which the subject is a member, and/or to society in general as a result of the research. **Such risks may be physical, psychological, spiritual, or social.** Assess the likelihood, severity, and duration of such risks. If the research methods create potential risks, describe other less risky methods, if any, which were considered, and explain why they will not be used. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject and the name and telephone number of the investigator. Include a statement that describes the plan for medical care or counseling in case an untoward event occurs.

8. A description of the means to be taken to minimize such risks including the means by which the subject's personal privacy is to be protected and the confidentiality of the information obtained from the subject maintained. Assess the likely effectiveness of such precautionary measures.
9. A description of the procedures to be used in obtaining and documenting the prior informed consent of the subject. If subjects are minors, subject "assent" must be obtained as well as parental/guardian informed consent. If written consent forms are to be used, a copy of the consent form (and/or a verbatim copy of any accompanying oral instructions) should be attached to the proposal. A copy of a suggested consent form "Consent for Child to Participate" is attached to these guidelines.
10. A description of how medical and/or counseling services will be provided if the subject suffers adverse health effects as a result of the research.
11. A "Waiver of Written Consent" must be requested from the IRB if the investigator does not wish to use a written informed consent. If a waiver of the requirement for written informed consent is sought, the justifications for the waiver must be specified.
12. If cover letters, questionnaires, interview schedules, or follow up communications are to be used in the research, a copy of each should be attached. If such are not available at the time of submission, an informative description of their content and manner of administration should be included in the proposal. The completed versions must be approved by the IRB PRIOR TO USE.
13. An explanation of any special or unusual circumstances regarding the research, which the principal investigator believes could be relevant to the IRB's decision in reviewing the project.
14. A copy of State and/or Federal documents, which permit the investigators to proceed if a new drug or device is to be tested or used in the project.
15. A proposal signed by the research advisor if research is to be conducted by student(s). The signature of the research advisor indicates acceptance of responsibility that the research will be conducted in accordance with ethical principles concerning the protection of the institution. **NO PROPOSAL WILL BE ACCEPTED WITHOUT SIGNATURE OF RESEARCH ADVISOR.**
16. It is the responsibility of the investigator to supply **one (1) copy of the proposal** (along with copies of the questionnaires, interview schedules, informed consent documents, and other supporting materials) to the IRB Chair.

# Flow Chart for Institutional Review Proposals



## EXPLANATION OF FLOW CHART FOR INSTITUTIONAL REVIEW

1. **Faculty** research proposal will be submitted directly to the Division/Department Chair, IRB Member or IRB Chair.
2. **Student** research proposal will first be approved by research advisor and then forwarded to the Division/Department Chair or designee, IRB Member or IRB Chair.
3. The Department Chair or designee will review the research proposal and if proposal is exempt, investigator will be notified of such by the IRB Chair.
4. If Department Chair or designee determines the research is not exempt then the proposal will be sent to the IRB Chair.
5. The IRB Chair will determine whether the proposal goes for full or expedited review.
6. If expedited review, three members of the IRB will be asked to do a review. If there is agreement between the three, then the IRB Chair will notify the investigator. However, if there is disagreement then the Chair of the IRB will send the proposal to a fourth member of the IRB to review. The Chair of the IRB will then notify the investigator and advisor of the decision.
7. If the IRB Chair determines that the research is not expedited research than the full IRB will review the proposal. The IRB Chair will notify the investigator and the advisor of the decision.