



INSTITUTIONAL REVIEW BOARD MANUAL

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Institutional Review Board

PURPOSE

Indiana Wesleyan University is committed to the protection of the rights and welfare of human subjects in all research, class projects and relative activities. The Institutional Review Board (IRB) upholds the standards of government agencies (Federal Regulations Title 45, Code of Federal Regulations, and Part 46). A copy of these standards can be found in the University Library, the office of Academic Affairs 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.

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 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 their 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 of benefit to participant, 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, six categories on pages four and five of the manual are exempt from the 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 on pages five and six of the manual. Expedited research is to be reviewed by two Human Subject Review 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 of 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.

STRUCTURE FUNCTION AND SCOPE

The code of federal regulations (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, and the Graduate School representing the University.

FUNCTION

The Board will uphold the Code of Federal Regulations 46.108 and function following the guide of 46.103. 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.

SCOPE

Research that is EXEMPT from Review

Some types of research, which are conducted by students or employees of Indiana Wesleyan University, are exempt from review by the Board. Academic division/department coordinators or their designees in cooperation with the principal investigators are empowered to determine whether a plan must be reviewed. No contact with the Board or application is required for projects which are exempt from review although documentation that the exemption has been approved is necessary. The Board, however, 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 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 if: (a) information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects at risk or criminal or civil liability or 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 (including observation by participants) or 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) 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 designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in 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 and for 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 or the United States Department of Agriculture.

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, 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 Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (a) programs under the Social Security Act, or (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.

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, uncannulated 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, 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, cognition game theory, 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.

PLEASE NOTE:

A **complete proposal** as defined in this document is necessary for all non-exempt, does not require a Board meeting, and approval can usually be granted within a week of receipt of the application.

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.

(The above was in large measure taken from "Instructions for Applying for Permission to Use Institutional in 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 Institutional as revised June 18, 1991.)

Appreciation is also expressed to Biola University, LaMirada, 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:

1. Include the completed IRB Proposal Checklist (see page 10).
2. A title page which conforms to the format (see page 11).
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 in the case that 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. 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 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.

IRB Proposal Check List

Submitted proposals will only be considered by the Institutional Review Board if the following elements are included:

- 1. Completed Proposal Title Page
- 2. Purpose of the research
- 3. Methodology
 - a. Subjects (how many, how selected or excluded)
 - b. Instruments
 - c. Procedures
- 4. Potential risks involved and methods of minimizing risks, inconveniences, or discomforts
- 5. All required forms (i.e. consent forms, letters of permission, and copies of instruments to be used)
- 6. Describe anticipated benefits and importance of the knowledge that may reasonably be expected to result.
- 7. IRB Proposal Checklist



PROPOSAL TITLE PAGE

(Specific Title of Research Project)

Check One:

_____ Faculty Research

_____ Student Research

Division/Department _____

Investigator

Street Address

City, State, Zip Code

E-mail Address (required)

Phone Number

Date

Investigator Signature _____

Research Advisor _____

Research Advisor E-mail _____

Research Advisor Signature _____



INFORMED CONSENT GUIDELINES

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. An investigator shall provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and minimize the possibility of coercion or undue influence. The information that is given to the subject representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution or its agent from liability for negligence.

HOW TO: The red text in the consent form template is intended to be instructions and helpful hints. When creating a consent form from the template below, please remove all text in red prior to submission to our office.

Also, please review the Additional Elements of Informed Consent and include any appropriate information in your consent form.

ADDITIONAL ELEMENTS OF INFORMED CONSENT

When appropriate, the following information shall also be provided to each subject:

1. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.
2. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.
3. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
4. Details regarding authorization for access to the subject's personal records (school, university, hospital, employment, or others).
5. Details regarding the use of tape recorders or other audio or visual recording methods, and an explanation of the proposed uses and disposition of such materials.
6. Always include, "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".
7. Significant new findings that may relate to a subject's willingness to continue participation
8. Approximate number of subjects in study.



RESEARCH PARTICIPANT CONSENT FORM

Title of Project

Principal Investigator's Name

Research Advisor's Name

Academic Division/Department

Purpose of Research (This statement should be easily understood by individuals with no prior knowledge of the area of study – avoid all jargon.)

Specific Procedures to be Used (This should include each step of the procedure the participant will either observe or experience.)

Duration of Participation (This should inform the potential participant of the number of days/hours they will be needed in order to participate.)

Risks to the Individual (Each study has some amount of risk. If the risk is minimal or similar to that of every day life, state that fact. If there is a chance you may become privy to information that must be reported, such as child abuse, child neglect, elder abuse or intent to harm self or others, this must be disclosed as a risk to participants.)

Benefits to the Individual or Others (Benefits refer to direct benefits to the participant. They need to be clearly stated. Not all studies will have direct benefits to the participant and if this is the case, it needs to be stated as so.)

Compensation (Compensations need to be listed here, they are not considered to be benefits. Delete this section if not applicable.)

Extra Costs to Participate (This could include, but is not limited to transportation costs to travel to the site of research, costs of medicine, etc. If there is no cost to the participant, state that fact.)

Injury or Illness (This should explain what the plan is for any medical situation that may occur during the research process. Explain who will be contacted and what the participant's rights are in terms of medical compensation. A plan for medical care should also be included.)

Confidentiality (Explain how the privacy and confidentiality of each participant will be protected. Include where, how, and for how long documents related to this study will be kept)

and how they will be eventually disposed of. Include the process of keeping audio/video tapes confidential (if applicable). It also needs to be stated if confidentiality is limited. For example, if you are meeting in focus groups, information shared may not be kept confidential by other group members. Also, there may be some information that is brought to light that you are required, by law, to report.) If subjects will be paid, the statement, "I understand that my name, social security number and address may be provided to the business office of Indiana Wesleyan University for the purpose of facilitating payment to me for participating in this study," should be included in this section as well.)

Voluntary Nature of Participation

I do not have to participate in this research project. If I agree to participate I can withdraw my participation at any time without penalty. (Explain how a participant would withdraw from participating without any penalty. If there is any circumstance that would make withdrawing difficult, that must be explained.)

Contact Information:

If I have any questions about this research project, I can contact (Insert Investigator's name and phone number plus any additional research personnel that participants may need to contact and their contact information. Also include the research advisor's name and contact information.) If I have concerns about the treatment of research participants, I can contact the Institutional Review Board (IRB) at Indiana Wesleyan University, Office of the Dean of the Graduate School, 1900 West 50th Street, Marion, IN 46953. (765) 677-2090.

*** Please note that all consent forms that are longer than one page must provide a space for initials and dates on all non-final pages.*

I HAVE HAD THE OPPORTUNITY TO READ THIS CONSENT FORM, ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND AM PREPARED TO PARTICIPATE IN THIS PROJECT.

Participant's Signature

Date

Participant's Name

Investigator's Signature

Date



Consent Form for a Minor to Participate

Child's Name: _____

Parent's/Guardian's Name: _____

I authorize (Name of Investigator) of (Division/Department) at Indiana Wesleyan University, Marion, Indiana, and any designated research assistants, to gather information from my child on the topic of (brief statement of research topic). I understand that my child's participation will involve: (list activities, i.e. answering questionnaires, interviewing, play activity, class work).

The study is unlikely to cause my child distress. I understand that I may withdraw my child from the study at any time AND that my child may decline to participate or terminate participation AT ANY TIME without penalty.

I understand that (Name of Investigator) will be available for consultation.

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.

Confidentiality of research results will be maintained by the research. No personally identifiable results will be released without the written consent of the parents or guardians of the particular child.

Signature of Parent/Guardian

Date

There are two copies of this consent form included. Please sign one and return it to the investigator. The other copy you may keep for your records.

Questions and comments may be addressed to (Name of Investigator) or (Name of Research Advisor), (Division/Department):

Indiana Wesleyan University
Graduate School
1900 West 50th Street
Marion, IN 46953
Telephone (765) 677-2090
irb@indwes.edu



**Institutional Review Board
Office of the Dean of the Graduate School
1900 West 50th Street
Marion, IN 46953**

Tel: 765-677-2090

Fax: 765-677-1456

_____ Date _____ Proposal Number _____ Reviewer

Your research proposal, with respect to the rights and safety of the human subject, has been evaluated as follows:

1. RISKS:

_____ The proposed research involves minimum risk and/or the subject's safety is adequately protected.

_____ The proposed research involves an element of risk to a vulnerable population and further measures seem advisable to protect the subjects, such as:

_____ The risk seems greater than can be justified by in research in that:

2. INFORMATION FOR THE SUBJECT:

_____ The information to be given the subjects (or their legal representatives) is complete and accurate enough for them to reach a valid decision concerning participation in the research.

_____ The information for the subjects as presented is incomplete or defective in that:

3. CONSENT METHOD:

_____ The format and manner of obtaining informed consent from the subjects (or their legal representatives) is satisfactory.

_____ The method of obtaining informed consent is defective in that:

4. FURTHER COMMENTS:

5. RECOMMENDATION:

_____ The proposed research is approved as submitted.

_____ The proposed research needs to be revised and resubmitted.

_____ The research as described is rejected.

Signature

Date



Institutional Review Board
Office of the Dean of the Graduate School
1900 West 50th Street
Marion, IN 46953

Tel: 765-677-2090

Fax: 765-677-1456

Notification of Exemption

_____ Title of Research Topic

_____ Investigator

I have reviewed your research proposal and have determined that:

Check One:

- _____ 1. Your proposal is exempt from further review by the IRB Committee.
- _____ 2. Your proposal is not exempt and must be forwarded to the Chair of the University Institutional Review Board for further review.

The reason your proposal is not exempt is:

Division/Department Chair or Designee, IRB Chair, IRB Committee Member

Date



Institutional Review Board
Office of the Dean of the Graduate School
1900 West 50th Street
Marion, IN 46953

Tel: 765-677-2090
Fax: 765-677-1456

NOTIFICATION OF APPROVAL TO CONDUCT RESEARCH

NAME OF INVESTIGATOR: _____

TITLE OF INVESTIGATION: _____

IRB ID NUMBER: _____

The Institutional Review Board of Indiana Wesleyan University has reviewed your proposal and reached the following decision.

The proposal has been:

_____ APPROVED AS SUBMITTED

_____ APPROVED PENDING SUBMISSION OF REVISIONS
(See below)

**ALL REVISIONS MADE MUST BE HIGHLIGHTED UPON
RESUBMISSION**

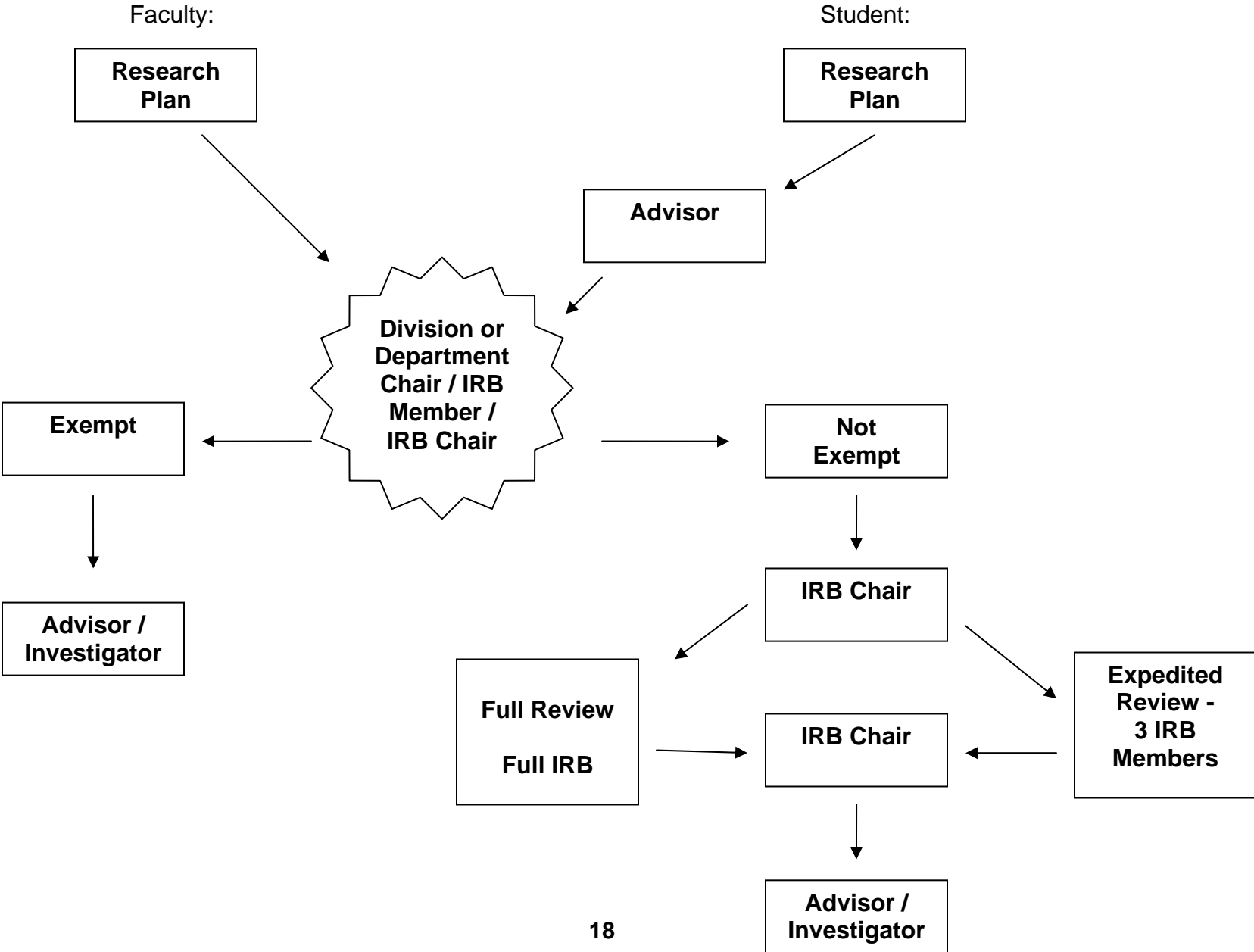
_____ NOT APPROVED (See below)

Comments/revisions required:

Signature: _____ Date: _____
Chair, Institutional Review Board

Reviewed by:

Flow Chart for Institutional Research Proposals



EXPLANATION OF FLOW CHART FOR INSTITUTIONAL RESEARCH

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.