

INDIANA WESLEYAN UNIVERSITY

HUMAN SUBJECTS REVIEW BOARD PROPOSAL

Institutional Review Board Chair

Dr. James Fuller, Dean of the College of Graduate Studies
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Indiana Wesleyan University

Human Subjects 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 Human Subjects Review Board (HSRB) upholds the standards of government agencies (Federal Regulations Title 45, Code of Federal Regulations, Part 46). A copy of these standards can be found in the University Library, the office of Academic Affairs and divisional offices.

Using these standards as a guide the HSRB 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 researchers 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 three and four of the proposal are exempt from the review if the subjects are eighteen years of age or older.

Academic 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 proposal. 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 Human Subjects Review Board.

STRUCTURE FUNCTION AND SCOPE

The code of federal regulations (46.107 IRB membership) guides the design of the Human Subjects Review Board. Board structure is drawn from Traditional, Graduate, and Adult and Professional Studies programs representing the University.

The representatives of the Board will be qualified through experience in conducting research. The Board structure will consist of the Chairperson of appointee from the following divisions/departments:

1. Division of Nursing Education
2. Division of Religion and Philosophy
3. Division of Education
4. Division of Behavioral Sciences
5. Academic Affairs
6. Adult and Professional Studies Research Coordinator
7. Student Development
8. Community Members
9. Division of Natural Science and Mathematics

FUNCTION

The Board will uphold the Code of Federal Regulations 46.108 and function following the guide of 46.103. Except for expedited review, the Board will meet to review proposals at a time, which the majority of the Board is present. Approval will be granted by a two-thirds majority agreement of the Board present at the meeting.

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 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 assistants 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 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 human subjects 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.
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 at a Regular Board Meeting (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 Human Subjects 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 Human Subjects as revised June 18, 1991.)

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

SAMPLE FORMS

INDIANA WESLEYAN UNIVERSITY GUIDELINES INFORMED CONSENT

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. 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 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.

Basic Elements of Informed Consent:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subjects.
3. A description of any benefits to the subjects or to others, which may reasonably be expected from research.
4. A statement describing the extent, if any, to which confidentiality or records identifying the subject will be maintained.
5. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained. This should include information such as an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in event of a research-related injury to the subject and the name and telephone number of the investigator. A statement should be included that describes the plan for medical care in the case that an untoward event occurs.

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. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. Details regarding authorization for access to the subject's personal records (school, university, hospital, employment, or others).
6. 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.
7. The amount and terms of any proposed payments or other form of remuneration to subjects.
8. 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".

INDIANA WESLEYAN UNIVERSITY CONSENT FORM FOR MINORS

Consent for Child to Participate

Child's Name: _____

Parent's/Guardian's Name: _____

I authorize (Name of Researcher) of (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 Researcher) 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 researcher. The other copy you may keep for your records.

Questions and comments may be addressed to (Name of Researcher), (Department):

Indiana Wesleyan University
4201 South Washington Street
Marion, IN 46953
Telephone (765) 677-2570

INDIANA WESLEYAN UNIVERSITY HUMAN SUBJECTS REVIEW

Guidelines for Submitting Research Plan To Division Chair/Appointee

All research done by representatives of Indiana Wesleyan University (faculty, staff, and students) that proposes to use human subjects must be approved by the Division Chair or appointee.

PROJECT TITLE:

INVESTIGATOR:

Address: _____

Phone: _____

DESCRIPTION OF RESEARCH

Attach a brief narrative with the following aspects in enough detail that the risk to human subjects may be assessed:

- A. Purpose of the research
- B. Methodology including:
 - a. Subjects-who, how many, how selected or excluded.
 - b. Instrument(s) – attach a copy of all materials to be given to subjects.
 - c. Procedures for data collection including consent process.
- C. Potential risks involved and methods of minimizing risks, inconveniences or discomforts.
- D. Describe anticipated benefits and importance of the knowledge that may reasonably be expected to result.

INFORMED CONSENT:

Attach a copy of the informed consent document to be used and a script of information if you plan to present a verbal explanation.

Signature of Investigator

Date

Signature of Research Supervisor

Date

INDIANA WESLEYAN UNIVERSITY HUMAN SUBJECTS REVIEW

DIVISION CHAIR RESPONSE

Title of Research Topic

Investigator

I have reviewed your research proposal and have determined that:

Check One:

- _____ 1. Your proposal is exempt.
- _____ 2. Your proposal is not exempt and must be forwarded to the Chair of the University Human Subjects Review Board.

The reason your proposal is not exempt is:

Division Chair Signature

Date

INDIANA WESLEYAN UNIVERSITY HUMAN SUBJECTS REVIEW BOARD

GUIDELINES FOR THE PREPARATION OF A PROPOSAL

A proposal is a WRITTEN STATEMENT, SIGNED BY THE PRINCIPAL INVESTIGATOR AND PROJECT DIRECTOR, which conforms to provisions 1 through 15 below.

The proposal, as approved by the Human Subjects Review Board, becomes part of the agreement between Indiana Wesleyan University and the researchers 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 HSRB's deliberations. Any change in the approved protocol, including supporting documents, must be approved by the HSRB. 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. A title page which conforms to the format (see page)
2. A summary of the nature and purpose of the research
3. 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.
4. A full description of exactly how the subjects will be used in the research
5. 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.
6. 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.

7. 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.
8. 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.
9. A description of how medical services will be provided if the subject suffers adverse health effects as a result of the research.
10. A "Waiver of Written Consent" must be requested from the HSRB if the researcher 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.
11. 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 HSRB PRIOR TO USE.
12. An explanation of any special or unusual circumstances regarding the research, which the principal investigator believes could be relevant to the HSRB's decision in reviewing the project.
13. 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.
14. 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 human subjects. NO PROPOSAL WILL BE ACCEPTED WITHOUT SIGNATURE OF RESEARCH ADVISOR.
15. It is responsibility of the investigator to supply three (3) copies of the proposal (along with copies of the questionnaires, interview schedules, informed consent documents, and other supporting materials) to the HSRB Chair.

SAMPLE PROPOSAL COVER PAGE

(Specific Title of Research Project)

Check One:

_____ Faculty Research

_____ In Partial Fulfillment for the _____ Degree, Indiana Wesleyan University

Department _____

Research Advisor _____

Investigator Signature _____

Research Advisor Signature _____

Date _____

Investigator

Street Address

City, State, Zip Code

Date

HUMAN SUBJECTS REVIEW BOARD BLIND REVIEW

_____ 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 be revised in keeping with above comments and resubmitted.

_____ The research as described is rejected.

Signature

Date

INDIANA WESLEYAN UNIVERSITY

NOTIFICATION OF APPROVAL TO CONDUCT RESEARCH

NAME OF INVESTIGATOR: _____

TITLE OF INVESTIGATION: _____

The Human Subjects Review Board of Indiana Wesleyan University reviewed your proposal on _____ (date) and has reached the following decision.

The proposal has been:

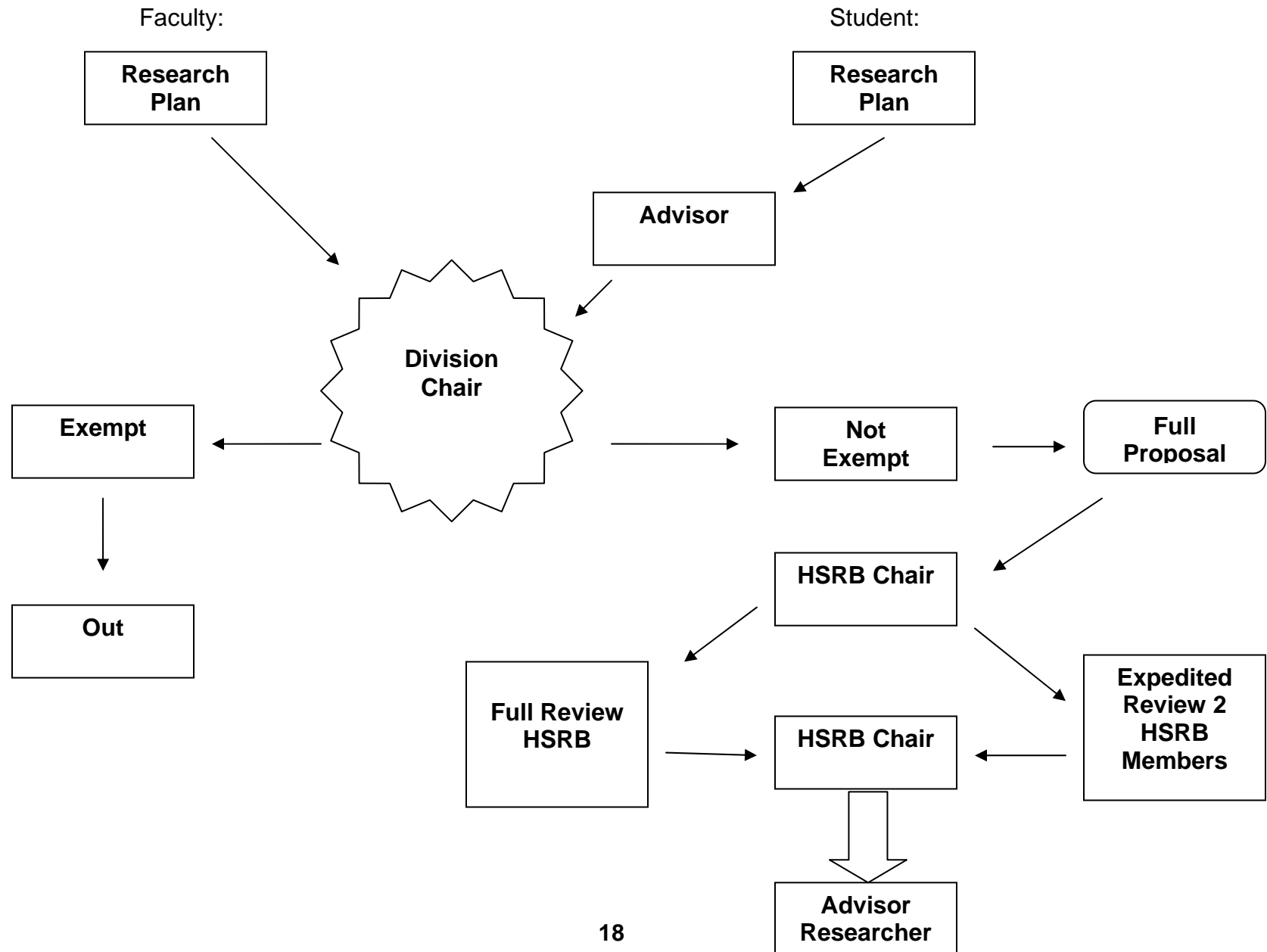
- _____ APPROVED
- _____ APPROVED WITH MODIFICATIONS (See Below)
- _____ NOT APPROVED (See attached explanation)

Comments/modifications required: _____

Signature: _____
Chair, Human Subjects Review Board

Date: _____

Flow Chart for Human Subjects Research Proposals



EXPLANATION OF FLOW CHART FOR HUMAN SUBJECTS REVIEW

1. Faculty research plan will be submitted to the Division Chair or appointee.
2. Student research plan will be approved first by research advisor and then forwarded to the Division Chair or appointee.
3. The Division Chair or appointee will review the research plan and if plan is exempt, investigator will be notified of such by the Division Chair or appointee.
4. If Division Chair or appointee determines the research is nonexempt then a full proposal must be prepared and sent to the Chair or the Human Subjects Review Board.
5. The HSRB Chair will determine whether the proposal goes for full or expedited review.
6. If expedited review, two members of the HSRB will be asked to do a blind review. If there is agreement between the two, then the HSRB Chair will notify the researcher. However, if there is disagreement then the Chair of the HSRB will send the proposal to a third member of the HSRB to review. The Chair of the HSRB will then notify the investigator/researcher advisor of the decision.
7. If the HSRB Chair determines that the research is not expedited research than full HSRB will review the proposal.