

**INSTITUTIONAL REVIEW BOARD (IRB)
FOR THE PROTECTION OF HUMAN SUBJECTS**

POLICIES AND PROCEDURES MANUAL

UNIVERSITY OF WISCONSIN-GREEN BAY

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INTRODUCTION

The University of Wisconsin-Green Bay encourages and supports free and responsible investigation by faculty, staff, and students. The policies and procedures of the University of Wisconsin-Green Bay for the protection of human subjects have been developed to protect the rights and welfare of human subjects. This guide contains instructions to assist you in the preparation of a protocol for submission to the IRB. The instructions on the following pages will help you to determine which parts of the protocol to complete and will explain the review process in detail.

UNIVERSITY OF WISCONSIN-GREEN BAY IRB REVIEW

Research projects that involve human subjects will require review by the University of Wisconsin-Green Bay (UW-GREEN BAY) Institutional Review Board (IRB) for the Protection of Human Subjects to determine if you have employed adequate measures to protect the subjects involved in your study.

The Office for Human Research Protection (OHRP) has published regulations governing Institutional Review Board (IRB) authority of research involving human subjects [Federal Register (June 18, 1991, 45CFR46), revised January 15, 2009 and effective July 14, 2009]. The University of Wisconsin-Green Bay adheres to these regulations.

For the purpose of IRB review, Federal Register defines *research* as 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.

Likewise, Federal Register defines a *human subject* as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

HUMAN SUBJECTS' PROTECTION TRAINING

The National Institutes of Health (NIH) requires all investigators or key personnel whose NIH-sponsored projects involve human subjects, or who assist in the design or execution of NIH-sponsored projects that involve human subjects, to complete training in human subjects' protection. The University of Wisconsin-Green Bay extends this policy by requiring all personnel with human subject involvement to take the training, regardless of the nature of their involvement and regardless of who sponsors the project.

The UW-Green Bay Human Subject's training consists of an on-line tutorial, which is available at: <http://www.uwgb.edu/irb>. The tutorial will provide the option to print a certificate of completion. A copy of the certificate must be attached to all protocols submitted to the IRB.

RESEARCH CONDUCTED AT ANOTHER FACILITY

If you are submitting a collaborative protocol with another facility and/or faculty/staff employed by another institution, that institution's IRB must approve the protocol prior to submission to UW-GREEN BAY's IRB, UNLESS you are the principal investigator on the project. Once you have obtained approval from the collaborating institution, submit a copy of the approved protocol, a copy of your instrument(s), UW-GREEN BAY's Coversheet, and the letter stating that the collaborating facility's IRB has approved your protocol. If you are the principal investigator on the project, it should first be submitted to UW-GREEN BAY's IRB.

REVIEW CATEGORIES

EXEMPT Protocol Submission

Introduction/Definition

EXEMPT means that the research, once approved, is exempt from further IRB oversight.

EXEMPT research is a category of research involving human subjects, defined by Title 45 Code of Federal Regulations Part 46, that does not require FULL BOARD review and approval. Please review the EXEMPT categories to determine if your research qualifies for EXEMPT status (page 4). You will be asked to cite the appropriate exemption number next to the EXEMPT box on the Protocol Submission Form and follow the procedures for EXEMPT review submissions on page 5.

EXEMPT Categories

These exemptions do NOT apply to research involving vulnerable groups (e.g., minors, prisoners, fetuses, pregnant women, human in vitro fertilization).

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education 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 [if minors are involved, full board review is required], interview procedures [if minors are involved, full board review is required], 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 already EXEMPT under #2 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 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, or pathological 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 [Federal] 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 these programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) 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.

Submission of EXEMPT Project Protocols

EXEMPT protocols must include the following:

1. A completed Protocol Submission Form (found on the UW-Green Bay IRB Website).
2. A Consent Form (as appropriate; see page 8).
3. All instruments/materials used for your research project (including surveys, interview scripts, etc.).
4. An IRB Training Certificate (researchers with a Training Certificate on file with the UW-Green Bay IRB do not need to submit one. Training Certificates can be obtained by completing the training on the UW-Green Bay IRB Website).
5. A Cooperating Institution Letter (Affiliation Letter), if applicable (see page 9).

Review of EXEMPT Research

1. Completed protocols should be submitted to the Institutional Review Board Chair for review by the Chair or designee. The Institutional Review Board will notify you when your protocol is approved. You may not begin your research until you receive the approval notification from that office.
2. If the IRB places a conditional approval on your protocol, you will not receive official approval until you submit the requested modifications to the Institutional Review Board. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year.
3. Once approved, you will not need additional review of your protocol unless you make modifications to your original protocol submission (see Protocol Modifications, page 8).
4. If the IRB Chair or designee determines that your protocol is not EXEMPT or needs clarification/modification, you will be notified and given instructions on how to proceed.

EXPEDITED Protocol Submissions

Introduction/Definition

If your project involves only minimal risk, but does not meet one of the six exemption criteria, your project may qualify for EXPEDITED review. Federal Register defines *minimal risk* to mean that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Submission of EXPEDITED Project Protocols

EXPEDITED protocols must include the following:

1. A completed Protocol Submission Form (found on the UW-Green Bay IRB Website)

2. A Consent Form (as appropriate; see pages 8).
3. All instruments/materials used for your research project (including surveys, interview scripts, etc.)
4. An IRB Training Certificate (researchers with a Training Certificate on file with the UW-Green Bay IRB do not need to submit one. Training Certificates can be obtained by completing the training on the UW-Green Bay IRB Website)
5. A Cooperating Institution Letter (Affiliation Letter), if applicable (see page 9).

Review of EXPEDITED Research

1. Completed protocols should be submitted to the Institutional Review Board Chair for review by the Chair or designee. The Institutional Review Board will notify you when your protocol is approved. You may not begin your research until you receive the approval notification from that office.
2. If the IRB places a conditional approval on your protocol, you will not receive official approval until you submit the requested modifications to the Institutional Review Board. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year.
3. If the IRB Chair or designee determines that your protocol does NOT qualify for EXPEDITED review and requires FULL BOARD review, you will be notified and given instructions on how to proceed.
4. If at any time you modify your protocol, you must submit those changes to the Institutional Review Board for review and approval by the IRB (see Protocol Modifications, page 8).
5. If your project continues for longer than one year, you will need to submit an ANNUAL PROGRESS REPORT (see Annual Progress Reports, page 8).

FULL BOARD Review Protocol Submissions

Introduction/Definition

If your project involves more than minimal risk to subjects as defined previously, your project requires a FULL BOARD review. Protocols involving any of the following will also require FULL BOARD review:

- Minor subjects (children 17 years of age or younger)
- Special populations (prisoners, pregnant women, individuals with disabilities)
- The use of video- or audiotape to record subjects
- Asking questions that may be highly embarrassing or compromising (e.g., sexual behavior, sexual orientation, alcohol consumption, illegal drug use, medical conditions, violations of the law, personal finances, problems in the workplace, etc.)
- Exposing subjects to graphically violent or pornographic materials
- Inflicting physical pain upon, attaching electrodes to, or injecting any substance into subjects
- Creating high levels of stress, fear, discomfort, or tension
- Threatening subjects in any way
- Causing subjects to violate laws or official university regulations

- Providing some subjects with benefits denied to others (this includes payments or rewards for participation, e.g., offering extra credit to participants, etc.)
- Causing physical or mental exhaustion or engaging subjects in intense exercise
- Placing individuals in confining physical settings or attaching other devices
- Exposing subjects to extreme conditions (e.g., bright lights, loud noise, intense pressure, strong odors, complete darkness, extreme heat or cold, sudden movement, etc.)
- Leaving subjects alone for periods of time longer than 20 minutes
- Taking hair samples or nail clippings from subjects
- Taking human tissue samples, drawing blood, or sampling any other bodily fluid

Submission of FULL BOARD Project Protocols

Protocols for projects, which require FULL BOARD review, must contain the following:

1. A completed Protocol Submission Form (found on the UW-Green Bay IRB Website)
2. A Consent Form (as appropriate; see pages 8).
3. All instruments/materials used for your research project (including surveys, interview scripts, etc.)
4. An IRB Training Certificate (researchers with a Training Certificate on file with the UW-Green Bay IRB do not need to submit one. Training Certificates can be obtained by completing the training on the UW-Green Bay IRB Website)
5. A Cooperating Institution Letter (Affiliation Letter), if applicable (see page 9).

Review of FULL BOARD Protocols

1. If your project requires FULL BOARD review, you must submit your protocol to the IRB Chair one week before the IRB meeting when you would like it considered. The IRB encourages you to attend the FULL BOARD review to provide any clarification the board may need. At the meeting, the IRB may approve, conditionally approve, disapprove, or table (e.g. due to insufficient information, concern about the research, etc.) your protocol. All meetings are contingent upon a quorum (including at least one member whose primary concerns are in nonscientific areas) of members attending.
2. After the meeting, the Institutional Review Board will notify you of the status of your protocol. If the IRB places a conditional approval on your protocol, you will not receive official approval until you submit the requested modifications to the Institutional Review Board. Once you have met those conditions, you will receive notification of condition fulfillment approving your protocol for one year.
3. If at any time you modify your protocol, you must submit those changes to Institutional Review Board for further review by the IRB (see Protocol Modifications, page 8).
4. If your project continues for longer than one year, you will need to submit an ANNUAL PROGRESS REPORT (see Annual Progress Reports, page 8).

PROTOCOL MODIFICATIONS

If you make any changes to your protocol, you must submit a Protocol Modification Form to the Institutional Review Board. If the modifications are minor (i.e., title change, agency change, addition of data collection sites, etc.) the IRB Chair or designee will review the protocol. If the modifications include more than minimal risk (see definition on page 5), the protocol will be included on the next IRB agenda for FULL BOARD review.

ANNUAL PROGRESS REPORTS

The IRB is required by 45CFR46 to conduct an annual review of every EXPEDITED or FULL BOARD IRB-approved protocol within 12 months of the original approval date. Complete the Annual Progress Report form and return it to Institutional Review Board. If your research project has been completed, you do not need to submit this form.

Annual Progress Reports are reviewed by the IRB Chair or designee. However, if modifications are made that include more than minimal risk (see definition on page 5), the protocol will be included on the next IRB agenda for FULL BOARD review.

INFORMED CONSENT PROCEDURES

Basic Elements of Informed Consent

- A. A statement that the study involves research, an explanation of the purpose 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.
- B. A description of any reasonably foreseeable risks or discomforts to the subjects.
- C. A description of any benefits to the subjects or to others, which may reasonably be expected from the research.
- D. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (if applicable).
- E. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
For example:
- F. For research involving more than minimal risk, an explanation as to whether any compensation is to be given and an explanation as to whether any medical treatments for injuries or counseling/psychological services for mental stress are available and, if so, what they consist of or where further information may be obtained.
- G. An explanation of whom to contact for answers to pertinent questions about the research (include the principal investigator/faculty advisor's name, Email address, and telephone number).
- H. An explanation of whom to contact for answers to pertinent questions about the research subject's rights/treatment (include the IRB Chairperson's name, Email address, and telephone number).
- I. A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- J. Informed consent may also require the following

- A. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
- B. A statement of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- C. A description of any additional costs to the subject that may result from participation in the research.
- D. An explanation of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- E. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

AFFILIATION LETTERS

Projects involving cooperating institutions must include an affiliation letter with each cooperating institution. The affiliation letter(s) should be written by a supervisor at the particular agency and serve as evidence that the primary investigator has been given permission to conduct research at the institution. You may not begin participant recruitment or data collection until you have submitted the signed affiliation letter(s) to the Institutional Review Board.

COURSE RESEARCH PROJECTS

If an activity or projects being conducted as part of a class qualifies as research with human subjects (see the definitions of *research* and *human subjects* on page 3), then IRB approval is required. However, in-class presentations do not constitute a contribution to generalizable knowledge. Thus, unless the intention is to present to an audience outside the institution, IRB approval is not required.

All course assignments involving human participants that do not fall under the category of research must still be planned and carried out with due consideration of the University's ethical and legal responsibility to protect individuals involved in these activities.

Keep in mind that unless the research requires FULL BOARD review, it can be evaluated relatively quickly, as is often needed for the classroom setting.