A Researcher’s Guide for Submission of Protocols

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This document is available on the following UWL web page:

https://www.uwlax.edu/grants/human-subjects-review-institutional-review-board-irb/

(Revised 09/2018 – discard previous guidelines)
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INTRODUCTION

The University of Wisconsin-La Crosse (UWL) Institutional Review Board for the Protection of Human Subjects (hereafter IRB) developed this guide to assist faculty, academic staff, and student researchers in the submission of protocols to the IRB. This guide is intended to introduce the investigator to the IRB, clarify the human subjects’ research review process, and simplify the preparation and review of research protocols.

IRB STATEMENT OF PURPOSE

The IRB is responsible for protecting the rights and welfare of human subjects participating in research projects. The IRB acts according to policies set forth by the United States Department of Health and Human Services Public Health Service Act as amended (Title 45 CFR PT 46). Compliance with these federal regulations not only safeguards human subjects and the institution sponsoring the research project, but also protects the researcher. The membership of the IRB, appointed by the Provost/Vice Chancellor with concurrence of the Chancellor, is composed of UWL faculty and community representatives. The Chair is a faculty member nominated by and directly responsible to the Provost/Vice Chancellor.

IRB GENERAL POLICIES

Any research that involves human subjects, whether funded or not, that is undertaken by a UWL faculty, academic staff or student or supported by the University of Wisconsin-La Crosse, must be reviewed by the IRB. Prior to collecting any data from any human subjects for research purposes or soliciting subjects for a research study, approval must be granted by the IRB. The IRB’s review of research will be based on the following general criteria.

A research protocol **MUST** be reviewed by the IRB under these guidelines if it meets all three of the following criteria: 1) it involves human beings as subjects; 2) it is research as defined on page 13; and 3) the intention to publish or disseminate results **OR** the **POSSIBILITY** of publishing or disseminating results exists. If a project meets these criteria, the protocol is then sent on to the IRB for expedited or full board review. If you have questions or concerns about your research project as it relates to these three criteria or the type of review your protocol may require, please call the IRB office at 785-8124 or email irb@uwlax.edu. The review shall determine whether or not human subjects will be placed at risk, and if risk is involved, whether or not:

1. risks to subjects are outweighed by the sum of the anticipated benefits to the subjects and the importance of the knowledge that is expected to result from the research;

2. risks to subjects are minimized by using procedures consistent with sound research design and ethical procedures;

3. informed consent from each prospective subject will be legally sought and obtained in accordance with the federal policy for the protection of human subjects; and

4. additional safeguards have been included to protect the rights and welfare of vulnerable populations (e.g., children, prisoners, persons with disabilities, pregnant women) who are necessary to the purpose and setting of the research.
EXEMPTIBLE RESEARCH

All research involving human subjects must be reviewed by the IRB; however, research activities that fall under any of the following federally defined exemptible categories will qualify for an IRB expedited review, and may not be subject to further IRB requirements (e.g., annual reviews, informed consent requirements; however, it is strongly suggested that written informed consent always be used). Investigators believing their research activities to be exempt must follow all procedures and specific requirements on pages 10-12 (Narrative Statement Guidelines and Guidelines for Submission of Protocols) of this guide.

The following types of research activities involving human subjects are defined by the federal government as exemptible research:

1. Research conducted in established or commonly accepted educational settings, and research that involves normal educational curricula 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 survey procedures, interview procedures, or observation of public behavior, except where any of the following conditions exist:
   a. Responses are recorded so that human subjects can be identified, either directly or through identifiers linked to human subjects; and
   b. any disclosure of the human subjects’ responses outside the research could reasonably place the subject(s) at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

3. Research involving survey procedures, interview procedures, or observations of public behavior if the human subjects are elected or appointed public officials or candidates for public office.

4. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, or achievement) if the information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.

5. 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 so that subjects cannot be identified.

6. Research and demonstration projects conducted by or subject to the approval of the Department of Health and Human Services and designed to study, evaluate, or otherwise examine:
a. Programs under the Social Security Act or other public benefit or service programs.

b. Procedures for obtaining benefits or services under those programs.

c. Possible changes in or alternatives to those programs or procedures.

d. Possible changes in methods or levels of payment for benefits or services under those programs.

EXPEDITED RESEARCH AND REVIEW PROCEDURES

Research projects which put human subjects at minimal risk or less may be eligible for an expedited review. Expedited reviews are conducted by the IRB Executive Committee, which meets on a regularly scheduled twice per month basis. To be eligible for an expedited review, the project must meet one or more of the following criteria.

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review\(^1\) procedure authorized by 45 CFR 46.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children\(^2\), considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution on the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt).

(8) Continuing review of research previously approved by the convened IRB as follows:
   (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

Children are defined in the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted”. 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1999

NOTE: Any research involving human subjects which does not meet at least one of the categories listed above, or puts subjects at more than minimal risk, or is not exemptible under categories listed on pages 4 and 5, must be reviewed by the Full IRB.
INFORMED CONSENT GUIDELINES

Obtaining the informed consent of a potential human subject for participation in any research (whether an experiment, survey, interview, or demonstration) is a federally mandated safeguard for protecting the rights and welfare of all individual subjects, and, in fact, constitutes the very essence of protecting those rights.* Therefore the IRB will very carefully review the method of obtaining and the content of informed consent listed below. When consent forms require signatures of research subjects and/or their parents or legal guardians, a copy of the fully signed form must be given to the subject/parent/guardian and a copy must be retained by the researcher for a minimum of three years after completion of the project. The consent form should avoid jargon and should be presented in lay persons’ language, and appropriate to the “audience.” Links to Model Consent Forms may be found on page 9. Be sure to adapt it to your specific project.

The consent form, headed with the title of the project, must include the following information in the sequence numbered 1-9 below:

1. Information on the purpose(s) of the research and a description of the method(s) and procedure(s) to be followed, including the intention to publish or disseminate, and the amount of time the subject will spend in actual project participation and where testing will take place,

2. A description of any reasonably foreseeable risks or discomforts to the subject and what will be done to address these if present; if disguised or deceptive procedures are used, a debriefing plan must be explained to the IRB,

3. A description of any benefits to the subject or to others as a result of the information obtained from the research,

4. A disclosure of appropriate alternative procedures that may be advantageous to the subject in making an informed decision whether or not to participate in the research (this pertains primarily to medical research and drug trials),

5. A description of the measures to be taken to insure the confidentiality of data and the anonymity of individual subjects, if applicable,

6. A clear explanation that participation is voluntary and that neither the refusal to participate nor the decision to discontinue participation (at any time) will involve no penalty or loss of benefits to which the subject is otherwise entitled.

*For survey research projects, informed consent is obtained by providing the potential subject/respondent a detailed explanation of the purpose for and the protocol of the research project. Completion of the survey instrument by the subject shall constitute informed consent, but this should be stated in the cover letter to the subjects or survey instructions.

7. Disclosure of costs to the subject, if any, because of his/her participation in the research; disclosure of compensation to the subject, if any, for his/her participation in the research.

8. The following statement must be used on the informed consent form when projects involve MORE than minimal risk. In the unlikely event that any injury or
illness occurs as a result of this research, the Board of Regents of the University of Wisconsin System, and the University of Wisconsin-La Crosse, their officers, agents and employees, do not automatically provide reimbursement for medical care or other compensation. Payment for treatment of any injury or illness must be provided by you or your third-party payor, such as your health insurer or Medicare. If any injury or illness occurs in the course of research, or for more information, please notify the investigator in charge. I have been informed that I am not waiving any rights that I may have for injury resulting from negligence of any person or the institution.

9. The name and phone number of a contact person(s) who will be available to answer any questions the subject or his/her legally authorized representative may have regarding the research (in addition to their own, student investigators must include the name, address, and phone number of his/her faculty research advisor), and “Questions regarding the protection of human subjects may be addressed to irb@uwla.edu.”

a. The consent form must include spaces for the signatures and dates for both the investigator and the human subject. If the subjects are children under the age of 18, spaces must be provided for the consent signatures of parent or guardian AND assent signature of the minor.

PLEASE NOTE: The consent form must NOT include a statement releasing the investigator, sponsor, institution or its agents from liability or negligence.

Sample Informed Consents

1. Standard suitable for most projects
2. Complex or higher risk projects
3. Projects with children with assent
NARRATIVE STATEMENT GUIDELINES

In order to ensure a timely review, investigators are encouraged to be brief, clear, and concise. The narrative statement of protocols must be typewritten and numbered according to the following requirements in the order in which they appear here. If a particular item does not relate to your study, indicate “not applicable” next to the item number.

The narrative statement of the protocol must include:

1. a brief description of the purpose of the proposed research project, including approximate beginning and ending dates of data collection. Include a brief and specific description of procedures and/or activities which subjects will undergo,

2. a description of the characteristics of the subject population in the project (e.g., number, gender, race or ethnicity [if known], age range, sampling frame, general mental and physical health, and any other unique characteristics) and an explanation of the rationale for using that particular population,

3. if relevant, a description of why any vulnerable populations are necessary to the research project (e.g., prisoners, children, persons with disabilities, pregnant women, or any group whose ability to give a voluntary informed consent may be questionable),

4. a description of how and where voluntary informed consent will be obtained from subject(s). You should include a copy of a final informed consent form, recruitment materials/posters, and final survey instrument or a list of interview questions along with this narrative statement.

5. a description of procedures to ensure the confidentiality of the subjects,

6. a description of any anticipated risks and/or inconveniences that might occur to the subjects as a result of participating in the research, including a statement of the approximate amount of time required of the subjects,

7. a description of procedures that will be used to minimize potential risk(s) to subjects and the probable effectiveness of those procedures, and

8. a description of any anticipated benefits that might occur for the subjects and any anticipated beneficial knowledge that might occur as a result of the proposed research project.
GUIDELINES FOR SUBMISSION OF PROTOCOLS

GENERAL PROCEDURES

1. Protocols must be typewritten and must be submitted electronically to irb@uw lax.edu in one continuous Word or PDF file in the following order:
   a. Attachment A
   b. Attachment B (if project is federally funded)
   c. Narrative Statement
   d. Informed Consent (and Assent if research subjects are minors)
   e. Survey instruments and other supporting material
   f. Any materials used to recruit study participants (i.e. posters, flyers, ads, etc.)
   g. Completion Certificate

2. All items of the narrative statement (page 10) must be numbered to correspond to each specific IRB requirement.

3. Researchers must address all issues contained within this guide, indicating “not applicable” where appropriate.

4. Researchers are strongly encouraged to have their protocols thoroughly reviewed by colleagues and/or faculty mentors, prior to submission to the University IRB.

5. Adequate time must be allowed for the IRB to review protocols. Generally, Expedited and Exempt protocols will be reviewed within three weeks while a Full IRB review may take a month to complete following their receipt.

6. IRB meeting dates are available on the IRB webpage.

7. Additional questions contact: irb@uw lax.edu.

SPECIFIC REQUIREMENTS

1. APPLICATION FOR UNIVERSITY IRB REVIEW (ATTACHMENT A) – Must include all required information and appropriate signatures.

2. Investigator’s NARRATIVE STATEMENT (see guidelines on page 10).

3. INFORMED CONSENT FORM to be used in the proposed project (for survey projects, a copy of the survey instrument/questionnaire must be included). If a cover letter is utilized, that too must be included.

4. Any supporting material/appendices that the investigator believes necessary for a thorough review of the proposed research protocol.

5. COMPLETION CERTIFICATE for the U.S. Office of Human Subjects Research Computer Based Training (CBT) tutorial. When UWL submitted a Federal Wide Assurance (FWA), in the summer of 2002, the university guaranteed that all researchers who were including human subjects would take a university mandated human subjects training course. Upon completion of the course, the researchers will be able to print out or save as a PDF a “Completion Certificate”. This certificate must be included as part of the protocol to be reviewed by the IRB. To be reviewed and approved,
protocols must have proof of current (not expired) training contained in the protocol or on file in the IRB office. UWL utilizes CITI for its IRB training. Information is available from UWL’s IRB page, which contains directions for creating a CITI account, completing training, and printing off the required documentation.

NOTE: the IRB, at its discretion, may require the completion of supplemental modules based on the nature or scope of the project and/or the demographics of the research participants. If required, a “Completion Report” that documents the completion of the additional modules must be on file in the IRB office prior to the start of the research.

6. If relevant: IRB DETERMINATION FORM FOR FEDERAL FUNDING AGENCIES (ATTACHMENT B); top section must be completed by investigator prior to submission.

7. If the project is a graduate thesis or project, the student’s Thesis Committee MUST have reviewed and approved the protocol PRIOR to the IRB review. This is indicated to the IRB by the signatures of Thesis Committee members and the signature of the thesis advisor on Attachment A, #2.c. In addition, all protocols related to undergraduate research should be reviewed by faculty advisors.

8. UWL IRB PROGRESS REPORT FORM (ATTACHMENT C) – If a project continues for more than 12 months from the time of IRB approval, the investigator must file a renewal request by filling out Attachment C and sending it, electronically along with any required accompanying documentation to irb@uwlax.edu. This MUST be done before the one year anniversary date of the letter from the IRB which authorized the project to commence.

9. Modifications to the research plan, subject pool, consent form or consent procedures, or any other significant changes to the study must be reviewed by the IRB. Attachment C may be used to communicate such changes.

10. Research conducted in cooperation with other agencies or organizations, e.g., La Crosse School District, Gundersen Lutheran, Franciscan Skemp, etc., may require review by those organizations’ IRBs and a letter of approval for the UWL IRB. Please contact us by sending an email to irb@uwlax.edu for advice in such situations.
GLOSSARY OF TERMS

Anonymity -- means that the identity of a subject is not identifiable with his or her responses.

Confidentiality -- refers to the treatment of information, that an individual has disclosed in a relationship of expectation that the information will not be divulged to others in a manner inconsistent with the understanding of the original agreement.

Continuing Review -- if data gathering continues for more than twelve months, federal regulations require that the project be subject to a "continuing review." Researchers should use Attachment C, the UW-L IRB Progress Report Form, on page 20 of this document. This form is also to be used if changes in the research protocol occur within any given twelve-month period.

Data Collection -- refers to any research procedure that is intended to elicit from or record the actions, reactions, attitudes, and/or behavioral manifestations of subjects participating in a research project.

Exemptible Research -- refers to human subject research activities that fall into one or more of the federally defined exempt research categories (see categories on pages 4-5). Exempt research does not mean the research protocols are exempt from IRB review, only that the research may qualify for an expedited IRB review, and may not be subject to other IRB requirements (e.g., annual reviews, informed consent requirements—however, it is strongly suggested that informed consent always be used).

Expedited Review -- refers to an IRB Executive Committee review of minimal risk or no-risk research proposals. See pages 6-9 for a listing of research activities which may be reviewed using the expedited procedure.

Full IRB Review -- refers to a review of proposals conducted by a majority of members of the IRB Committee.

Human Subject -- refers to a living individual from whom a researcher obtains either identifiable private information or data through intervention and/or interaction with the individual.

Informed Consent -- refers to the voluntary agreement by an individual or an individual’s legally authorized representative to participate in a particular study without any element of force, fraud, deceit, duress, or any other form of constraint or coercion. Valid consent requires voluntary action, competence, informed decision, and comprehension of terminology.

Minimal Risk -- means that the probability and magnitude of harm(s) or discomfort(s) anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

Multidisciplinary Research -- refers to research that investigates a phenomenon in more than one area of academic study.

Research -- refers to a systematic investigation designed to develop or contribute to generalized knowledge. It is understood that such research will be disseminated by publication or in a public or professional forum.

Vulnerable Populations -- refers to subjects such as children, prisoners, pregnant women, persons with disabilities, economically or educationally disadvantaged persons, or any other population that may be relatively or absolutely incapable or protecting their interests through the informed consent process.