UNIVERSITY OF WISCONSIN
LA CROSSE UWL

A Researcher's Guide for Submission of Protocols

Institutional Review Board for the Protection of Human Subjects

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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.

ADDITIONAL INFORMATION

A copy of this guide, along with other IRB resources, is available at

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

CONTACTS

IRB Program Assistant:

Nikki Pegarsch, Research & Grants Program Assistant, 608.785.8044, irb@uwlax.edu

- Protocol submission and review process
- Training and survey tools
- Institutional documentation, including reliance agreements

IRB Coordinator:

Bart Vanvoorhis, Associate Professor, 608.785.6892, bvanvoorhis@uwlax.edu

- Narrative requirements
- Review of research protocols
- Federal policy

IRB Institutional Oversight / Research Integrity Officer (RIO):

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- Institutional compliance
- Policy oversight

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 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 or their designee with concurrence of the Chancellor, is composed of UWL faculty and community representatives. The Chair is a faculty member nominated and elected by the IRB voting members and directly responsible to the Provost/Vice Chancellor or their designee.

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, which is defined as 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.
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 either 1) determination to be exempt from review OR 2) 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 785-8044 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, individuals with impaired decision-making ability) who are necessary to the purpose and setting of the research.

IRB Human Subjects Training Course

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 each protocol a researcher submits to be reviewed by the IRB. **UWL utilizes CITI for its IRB training.** Information is available from UWL's IRB webpage, including directions for creating a CITI account, completing training, and obtaining 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.

PARTICIPANT INCENTIVES*

Incentives may be used as a recruitment tool to offset the time and inconvenience of participation. While there are no limits on incentives to participants, researchers and the IRB must ensure that research subjects provide voluntary, informed consent that is free from coercion or undue influence. State and university policies dictate processes that must be used and limits on the amount and type of incentive offered based on the funding sources and residency status of the participant.

Visit the Payment of Incentives to Research Participants website for more information. Incentives are exactly that - an incentivization to participate. They should never be referred to as "compensation" or described on a "per hour" or "minimum wage" basis. These references could imply an employer-employee relationship, which is not the basis of their involvement in the project, and could alter requirements under IRS regulations.

Types of Incentives

Incentives can take on many forms that are monetary and/or non-monetary.

- Monetary incentives include cash, checks, and gift cards.
- Non-monetary incentives can include no value items, small value items (less than $10), or other research-specific items (such as an item used as part of the research).
- Extra credit can be offered for student subjects.

- Drawings, raffles, and other "chances to win" maybe be used, but there are restrictions (see below).

Monetary and non-monetary incentives. Incentives should not require subjects to spend their own money. For example, a gift card to a coffee shop would be acceptable if it was sufficient to purchase a drink or other items without spending additional money. However, a 50% off coupon would not be appropriate. Note: non-resident aliens, which are sometimes referred to as NRAs, are restricted by IRS regulations to only receiving monetary incentives as checks from the research sponsor (e.g. UWL) and non-monetary incentives including no value, small value, research-specific items, and extra credit.

Variable incentives. Incentives do not need to be equal as it may be awarded or accrued by participants in response to various tasks in a study. For example, incentives may be increased or decreased in the process of playing a game where certain decisions have a differential outcome. For these studies, participants should be informed of the minimum and maximum amounts they may receive for their involvement in the research in the informed consent documents.

Extra credit. For student subjects, reasonable levels of extra credit may be offered as incentive for participating in research. If extra credit is offered, students must be provided with and informed of non-research alternatives involving comparable time and effort to obtain the extra credit for the possibility of undue influence to be minimized.

Drawings, raffles, and other "chances to win". These offers may also be used as an incentive, but a researcher should consult with the Office of Research & Sponsored Programs to determine allowability. GPR (e.g., 102, 131) dollars are never permitted to be used as a prize for a drawing or chance to win. Also, there are limits as to the amount of the prize relative to the amount of effort that is expected of a participant. High effort expectations coupled with a small chance at a large prize may cause issue via an IRS rule known as consideration, which could generate a substantial financial obligation for the researcher.

Appropriateness of Incentives

All potential research participants and/or their parent/guardian should be able to make informed decisions about participation based on the true risks and benefits of the research, not based on compensation. Incentives that are excessive or inappropriate in relation to the research procedures is problematic because it can induce subjects to participate against their better judgement or encourage some individuals to lie or withhold information in order to participate. Inappropriate incentives can also create coercive situations when given to third parties. For example, a parent may coerce their child into participating in a study when payment is significant. Excessive or inappropriate incentives not only impact the integrity of the research and the validity of the data, but they can also compromise the safety of subjects.

Timing of Incentives

In addition to the form and amount of incentive to the participants, researchers should consider the timing of payments. **For research procedures that occur once for a short period of time,** it may be appropriate to make receipt of the incentive contingent upon completion. However, if a subject is disqualified during the study or is unable to complete the research through no fault of their own, they should still receive the incentive.

In other studies, participation involves tasks completed over time or through multiple interactions or interventions (e.g., a one-hour interview done once a month for three months). Making the receipt of the incentive entirely conditional on the completion of multiple procedures could undermine a participant's ability to withdraw at any time. In most cases, payments should be prorated, and subjects who are not able to complete the research should receive an incentive proportional to their participation, regardless of whether they withdraw or are withdrawn by the researchers. Prorating payments to subjects is required for FDA-regulated research. Researchers are allowed to withhold a portion of the incentive until completion (e.g., a completion bonus), provided that the amount does not exceed more than 50% of the total incentive.

Compensation for Research-Related Injury

If research-related injury (i.e., harm that is physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given of whatever voluntary compensation and treatment will be provided in the informed consent. Note that the federal regulations do not limit injury to only physical injury – (45 CFR 46.102(g)).

Information Collected for Accounting and Reporting Purposes

It is the responsibility of the researcher and/or their faculty mentor to maintain accurate incentive distribution records in accordance with UWL policy. The IRB should be informed of any required collection of subject information (e.g., name, email, SSN, student ID, etc) for accounting purposes in #9 of the narrative statement.

Currently, this collection is mandated to be compliant with federal and state income tax reporting requirements:

- **For participants who are non-resident aliens (NRAs)**, the PI must have the participant complete an IRS Form W-8BEN regardless of the total incentive payments that may be made to the individual. Payments must be reported by the individual to the IRS (on Form 1042-S) and could be subject to 30% federal income tax withholding.
- **For participants who are US tax residents,** if the PI is providing a single payment, cash or gift card, of $50 or more **OR** is aware that incentive payments to an individual are likely to total $600 or more during a calendar year, the PI must

have the participant complete an IRS Form W-9. Payments must be reported by the individual to the IRS (on IRS Form 1099-MISC in Box 3, Other Income).

Note: Students may NOT collect, view, handle, or be in possession of W-9 or W-8BEN forms for research participants. NO EXCEPTIONS. If a PI requires assistance to obtain or appropriately secure this information, another UWL employee, who is not a student, may assist even if they are not otherwise attached to the project. If a student is conducting research that requires collection of this data, they must have the data collected by a UWL faculty or staff member.

Disclosures to Research Subjects

Research subjects should be accurately informed through the consent process about any incentive for participation. The consent form should clearly state what form of payment will be provided, the amount or value of the payment, and the timing of the incentive. If or when questions or complaints arise regarding incentive payments, the consent form becomes the source document for the information that was provided to participants. The information about incentives should be clear, detailed, and consistent with your protocol.

In the case of drawings, raffles, or other chances to win, potential participants need to be informed of the odds of winning (i.e., how many individuals are participating divided by the number of prizes), how participants can enter the drawing, how winners are chosen, and how winners are notified.

In any study where information is being collected from participants for accounting purposes, individuals need to be informed about what information will be requested (e.g., name, email, SSN, student ID, etc.) and how that information will be used and stored, including any reporting to the Internal Revenue Service. Do not, however, provide any statement that sounds as though you are providing legal or tax advice. Some examples of consent form language include:

- "Financial rules require us to have your XXX [e.g., name, SSN, address] in order to pay your participation incentive. This information and your payment amount will be kept secure and confidential in our research financial records, our department's financial office, and the University's financial office. This information will not be associated with the study name or the research data you provide as a participant."
- "If you are paid a total of $600 or more as a research subject in a calendar year, the University is required to report the payment to the Internal Revenue Service as miscellaneous income. UWL will send you a form (IRS form 1099) in January documenting the payment total. This form is also sent to the IRS to report any money paid to you. You can use the form with your income tax return, as appropriate."

*This section was adapted from the Metropolitan State University in Denver's IRB website.

SINGLE IRB / RELIANCE AGREEMENTS

Cooperative research projects are covered in 45 CFR 46.114:

> (a) **Cooperative research projects are those projects** covered by this policy [that] **involve more than one institution**. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.
>
> (b)(1) **Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States**. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
>
> (2) **The following research is <u>not</u> subject to this provision:**
>
> > (i) **Cooperative research for which more than single IRB review is required by law** (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
> > (ii) Research for which any **Federal department or agency** supporting or conducting the research **determines and documents that the use of a single IRB is not appropriate** for the particular context.
>
> (c) For research not subject to paragraph (b) of this section, **an institution participating in a cooperative project may enter into a joint review arrangement**, rely upon the review of another, or make similar arrangements for avoiding duplication of effort

Reliance Agreements

When UWL will be one of several sites for research or a UWL investigator will be working with investigators from other institutions/entities on human subjects research, a written agreement must be used to specify the delegation of review responsibilities. UWL refers to these agreements as an IRB reliance agreement, but they are also referred to as IRB authorization agreements or cede review agreements.

For example, research conducted in cooperation with the La Crosse School District, Gundersen Health System, Mayo Clinic Health System, etc., may require review by those organizations' IRBs and a reliance agreement with the UWL IRB. Please contact us by sending an email to irb@uwlax.edu for advice in such situations.

When UWL is the IRB of record, other institutions will be relying upon UWL to provide IRB review and oversight. If this is the case, you may not use the Exempt Decision Tool. The following will be required:

1. The reliance relationships must be described in #10 of the narrative statement. Include a list of the investigators, their institutional affiliations, and, if different, the

responsibilities each investigator will have with respect to the human subjects' portion of the research project.
2. The UWL investigator must contact the UWL IRB office and request a UWL reliance agreement template.
3. Before beginning work on their portion of the human subjects' research, each non-UWL institution must have a fully executed UWL reliance agreement on file with the UWL IRB before their investigator(s) may begin work on a protocol approved by UWL's IRB.

When UWL is deferring to another IRB of record, UWL will be relying upon another institution's IRB to provide protocol review and oversight. The following will be required:

1. The UWL investigator(s) must email the UWL IRB to inform the office of the research protocol. That email should include both the name of the lead investigator and their institutional affiliation.
2. When deemed appropriate by the IRB of record, the UWL investigator(s) must provide the UWL IRB with the required reliance agreement paperwork from that institution. If that institution does not have reliance agreement templates, the UWL investigator(s) may request a reliance agreement for deferring to another institution template from the UWL IRB office.
3. The UWL investigator(s) must have a fully executed reliance agreement on file with the UWL IRB prior to beginning any work on a protocol approved by a non-UWL IRB.

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 use of an IRB expedited review or, in many circumstances, use of the IRB Exempt Decision Tool, 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 either complete the IRB Exempt Decision Tool and receive an affirmation email from the tool that the protocol is exempt from further review unless changes are made OR follow all procedures and specific requirements for the submission of a protocol**. If a protocol is submitted, it will generally be reviewed using expedited review procedures. NOTE: neither researchers nor their mentors are permitted to deem their own human subjects research as being exempt from any review.

Applicability/ Research Categories

The following types of research activities involving human subjects are defined by the federal government as exemptible research. UWL policy excludes the use of the exempt definition for any research involving participant incentives and/or vulnerable

populations including children, prisoners, and individuals with impaired decision-making ability.

Per 45 CFR 46.104(d), exempt research is defined as meeting one or more of the following human subjects research categories:

1. **Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction**. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **Research that only includes interactions involving educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures, or observation of public behavior** (including visual or auditory recording) **if <u>at least one</u> of the following criteria is met:**
    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (<u>Note: this research category is not eligible for using the Exempt Decision Tool</u>.)
3. **Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and**
    a. **<u>at least one</u> of the following criteria is met**:
        i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
        ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
        iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (<u>Note: this research category is not eligible for using the Exempt Decision Tool</u>.)

b. **For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing**. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
c. **If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deceptio**n through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. **Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if <u>at least one</u> of the following criteria is met:**
   a. The identifiable private information or identifiable biospecimens are publicly available;
   b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
   c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
   d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*
5. **Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads** (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), **and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including**

procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

   a. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. **Taste and food quality evaluation and consumer acceptance studies:**
   a. If wholesome foods without additives are consumed, or
   b. 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.
7. **Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).** (Note: this research category is not eligible for using the Exempt Decision Tool.)
8. **Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:** (Note: this research category is not eligible for using the Exempt Decision Tool.)
   a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
   b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
   c. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
   d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

IRB Exempt Decision Tool

For exemptible research categories 1 through 6 above, that do not involve vulnerable populations, the IRB Exempt Decision Tool is available for UWL faculty, staff, and students to seek an exempt status designation for a research project involving human subjects. Exemptions are only valid if requested by and granted to a current UWL employee or currently enrolled UWL student.

Important notes:

- **Students must have mentor/advisor approval** before using this decision tool.
- **The tool may not be used if:**
    - **other institutions will be relying upon UWL's IRB** to provide review and oversight
    - **participant incentives** are being offered
    - **exemption is being claimed under exemptions research categories numbered** 2.c., 3.a.iii., 7, and/or 8.

Prior to using the survey tool, researchers should:

1. complete the mandatory CITI training for Human Subjects Research and create a pdf of the completion certificate,
2. review this guide to ensure that the research meets the definition of exemptible research and is eligible for using the IRB Exempt Decision Tool, and
3. review the IRB Exempt Decision Tool Preview available on the IRB website in preparation to be able to answer the questions asked.

You may choose to upload any additional materials about your survey that you wish to be part of the record. This could include sample interview questions, informed consent documents, etc. If you are providing these materials, they must be in a single pdf document which will be uploaded near the end of the survey. NOTE: Due to the nature of the Exempt Decision Tool, these materials will not be used to determine whether your protocol is exempt and may or may not be reviewed during process audits.

DO NOT GUESS on any of the answers in the survey. If you are unsure how to answer a question, reach out to an advisor, colleagues, or the IRB, and return to complete the survey.

After completing the Exempt Decision Tool, researchers will receive an email either declaring their project, as described, as exempt from further review or directing them to submit a protocol narrative to irb@uwlax.edu for review. If directed to submit a protocol, follow the directions found under the section of this document titled "Guidelines for Submission of Protocols." Exempt protocols are reviewed under expedited review procedures and timelines.

For more information on this tool, please go to https://www.uwlax.edu/grants/human-subjects-review-institutional-review-board-irb/

EXPEDITED RESEARCH AND REVIEW PROCEDURES

Research projects that put human subjects at no more than minimal risk may be eligible for an expedited review.

Applicability

1. 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.
2. The categories in this list apply regardless of the age of subjects, except as noted.
3. **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.
4. The expedited review procedure **may not be used for classified research** involving human subjects.
5. 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.
6. Research categories one (1) through seven (7), listed below, pertain to both initial and, if required, continuing IRB review.

Research Categories

To be eligible for an expedited review, the project must meet one or more of the following criteria:

1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**

[1] 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.

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 non-disfiguring 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. uncannulated 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 sub-gingival 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.

[2] 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).

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 non-research 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.** Note: this applies to research that cannot qualify as Exempt under item #2.
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.

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 in this guide, must be reviewed by the Full IRB.

Expedited Review Procedures

To submit a protocol for expedited review, you must follow the directions for an electronic submission found under the section in this document titled "Guidelines for Submission of Protocols."

Expedited reviews are conducted by the IRB Coordinator and select members of the IRB Committee on an ongoing basis during the fall and spring semester and intermittently throughout the summer. Allow adequate time for IRB review. See the IRB website for estimated review times.

FULL PROTOCOL REVIEW PROCEDURES

If your research does not qualify for exempt or expedited review, the protocol must be reviewed by the full IRB committee.

To submit a protocol for expedited review, you must follow the directions for an electronic submission found under the section titled Guidelines for Submission of Protocols.

The IRB committee meets 3 Friday mornings each fall and spring semester. See the IRB website for the established dates. To be placed on the meeting agenda, the complete protocol must be received by the end of the business day, no later than 4:30 pm, on the preceding Friday. Researchers are expected to attend the IRB meeting to describe and answer questions regarding their research protocol. Within 1 week of the meeting, the researcher(s) will receive a letter indicating the decision of the IRB committee.

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, should be presented in lay persons' language, and should be appropriate to the "audience."

Model consent forms may be found on the IRB website. Consent form examples can also be obtained by talking with mentors or colleagues who have conducted similar projects. Be sure to adapt any example to the specific project.

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. Any other relevant information from the consent form list numbered 1 to 11 below should be included in the cover letter or survey instructions. Completion of the survey instrument by the subject shall constitute informed consent, but this should be explicitly stated in the cover letter to the subjects or survey instructions.

Required Components

The consent form, headed with the title of the project, must include the following information in the sequence numbered 1-11 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;

7. Disclosure of **costs to the subject**, if any, because of their participation in the research;

8. Disclosure of any **participant incentive** to the subject, if any, for their participation in the research, and, if varying amounts may be received, the calculation and/or or timing of those amounts must be explained;

9. **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.

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

11. 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.

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

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 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., children, prisoners, individuals with impaired decision-making ability, 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;**
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;
9. If relevant, a **description of any participant incentives** that will be offered/given to the research subject(s). They should never be referred to as "compensation" or described on a "per hour" or "minimum wage" basis. If participants may receive different amounts or will be receiving the incentive in installments, the calculation or timing of those amounts must be explained. Also describe what, if any, information will be collected (e.g., name, email, SSN, student ID, etc.) for payment and accounting purposes;
10. **If other institutions will be relying on the UWL IRB protocol review**, include a list of investigators, their institutional affiliations, and, if different, the responsibilities each investigator will have with respect to the human subjects' portion of the research project. (Note: A fully executed reliance agreement must be on file

with UWL's IRB for each institution before their investigator's human subjects research may begin.)

GUIDELINES FOR SUBMISSION OF PROTOCOLS

1. Protocols must be typewritten and must be submitted electronically to irb@uwlax.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 (e.g., posters, flyers, ads, etc.)

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

    h. CITI Completion Certificates for all listed investigators, with the lead investigator placed first

2. All items of the **narrative statement** (see guidelines) 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/mentors prior to submission to the University IRB.

5. Students must have approval from their mentor, advisor, and/or thesis committee before submitting a protocol for IRB review.

6. 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.

7. The IRB has 3 scheduled meetings each fall and spring semester to conduct business and full protocol reviews. Dates are available on the IRB webpage.

8. Additional questions contact: irb@uwlax.edu.

REQUIREMENTS FOR MODIFICATIONS OF PROTOCOLS

1. Complete **Attachment C, UWL IRB Revision or Report Form**. This form can be used to report 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.
    a. **Request approval of protocol changes** (expedited or full) – attach description of requested changes. If necessary, include updated supplementary documents
    b. **Request approval of consent form changes** (expedited or full)- attach description of changes and/or revised consent/assent documents
    c. **Report study closure** (full) – note this on the form in the relevant question
    d. **Report end date changes; early closure or extension of the end date** (expedited and full) – note this on the form in the relevant question
    e. **Report change in lead PI/PD** (expedited and full) – note this on the form in the relevant question. If this person's CITI IRB training certificate was not previously submitted with this protocol, include it with Attachment C.
    f. **Report adverse event(s)** (expedited and full) – submit all information necessary for the IRB to review the adverse event that occurred with your research
    g. **Report annual continuing review** (required for full; only if a condition of approval for expedited) – complete all sections of Attachment C, attach any documentation required by the form
2. **Include any supporting material/appendices** that is listed above and that the investigator believes necessary for a thorough review of the proposed research protocol.
3. **Attachment B, IRB DETERMINATION FORM FOR FEDERAL FUNDING AGENCIES**, should be completed and submitted with the original protocol submission along with Attachment A. However, **if funding sources change to include federal** dollars, whether direct or as pass-through, Attachment B must be submitted and its acceptance acknowledged by the IRB and ORSP prior to the expenditure of any federal funds on the research protocol.

APPENDICES

Glossary of Terms

Anonymity -- means that the identity of a subject is not identifiable with their responses.

Children – per HHS regulations "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))

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 for 1) a protocol that underwent expedited review and had a stipulation of continuing review or 2) a protocol that underwent full review, federal regulations require that the project be required to submit no less than annual updates on the progress of the research being conducted. Researchers should use Attachment C when submitting information for the continuing review.

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 under Exemptible Research). Exempt research does not mean that the research is exempt from all IRB oversight, but that the research may qualify for designation as exempt from further review and may not be subject to other IRB requirements (e.g., 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 Expedited Research and Review Procedures 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.

Participant Incentive -- a recruitment tool to offset the time and inconvenience of participation. An incentive may be monetary or non-monetary in nature.

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, individuals with impaired decision-making ability, 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.

COVID-19

An IRB protocol or other research procedures may NOT be used as a reason to bypass or subvert state, local, or university safety requirements.

- Masks must be worn.
- Maintain a distance of at least 6 feet. If this is not possible, closer contact should not exceed 15 minutes.
- Sanitizer must be available.
- Additional protocols required in individual labs (e.g., using hand sanitizer upon entering or exiting a lab) must be followed.