University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 2 Effective Date: 10/19/2019 Last Reviewed: 10/10/2022 Prepared By: K. Schill, M. Bublitz Updated: 10/4/2022	**Title:** **IRB Review Process and Responsibilities of Researcher and IRB**

IRB Review Process and Responsibilities of Researcher and IRB

The goal of this standard operating procedure is to provide information on 1) the process and requirements for submitting an IRB Application, 2) the IRB review process, and 3) researcher responsibilities once a study is approved.

I. UW Oshkosh IRB Application Process

A. Review SOP #1: Determining Whether a Project Requires IRB Review to determine if your project requires submission of an application for IRB review.

B. Complete the appropriate application form:
https://uwosh.edu/sponsoredprograms/irb/forms/

1. **IRB Protocol Application for New Projects** (Collection of new data)
2. **Existing Human Subjects IRB Data Form** (Existing data or biospecimens)
3. **Course Umbrella Protocol Application** (Summary of varying individual student projects within a course)

To ensure the IRB can understand the details presented in the IRB Application, please enter information clearly, concisely, and consistently throughout the application sections and in the associated study documentation.

C. Complete the required CITI Program human subjects research tutorial(s):

1. Submit completion report certificate(s) along with your application: Training requirements may be located here:
https://uwosh.edu/sponsoredprograms/irb/training/

D. Attach Study Documentation/Appendices to IRB Application Form

1. Attach Appendices as Applicable: abstract, recruitment materials, consent form, interview questions/questionnaire, study forms, debriefing/information statement, site permission, training certificates, and applicable supplemental information to assist with the review at the end of the application form

II. IRB Initial Review Process for a New Study

(See Appendix 1: IRB Review Process Flow Chart)

A. Exempt Determinations and Limited IRB Review

1. An IRB Application must be submitted for all human subjects research activities (See SOP #1: Determining if IRB Review is Required), including studies that meet criteria for exempt status. Experienced IRB staff or IRB members will make the determination on whether research activities meet the criteria for exempt status. In addition, some activities require ***Limited IRB Review*** to make the determination required by CFR 46.111(a)(7) which states that adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data are in place.
2. In order for a study to be determined to be exempt, all research activities must fit into 1 or more of the following exempt categories:
   - Exempt Category #1 .104(d)(1):
     Research, conducted in established or commonly accepted educational settings, which 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 comparison among, instructional techniques, curricula, or classroom management methods.
   - Exempt Category #2 .104(d)(2):
     Research that includes only interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of following criteria are met:
     - 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;
     - 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
     - the information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited review** to make the determination required by 45 CFR 46.111(a)(7) (when appropriate, there are adequate provisions for protecting privacy and maintaining confidentiality of data).
   - Exempt Category #3 .104(d)(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 <u>at least one of the following criteria are met</u>:

- 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;
- Any disclosure of the 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
- 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 subject, and an IRB conducts a **limited IRB review** to make the determination required by 45 CFR 46.111(a)(7)

- <u>Exempt Category #4 .104(d)(4):</u>
  Secondary Research Use of Identifiable Private Information and/or Identifiable Biospecimens for which consent is *Not* required, if <u>at least one of the following criteria is met</u>:
  - The identifiable private information or identifiable biospecimens are publicly available; OR
  - The information is recorded by the investigator in such a way that the identity of the subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact subjects, and the investigator will not re-identify subjects; OR
  - The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA 45 CFR parts 160 and 164, subparts A and E (i.e., the use is regulated for purposes of "health care operations" or "research" as those terms are defined at 45 CFR parts 164.501 or for "public health activities and purposes" as those terms are defined at 45 CFR part 164.512 (b)); OR
  - 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 certain federal statutes.

- Exempt Category #5 .104(d)(5):
  Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency:
    - Applies to 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. Applies to activities that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including, but not limited to: 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.
- Exempt Category #6 .104(d)(6)
  Taste and Food Quality Evaluation and Consumer Acceptance Studies:
    - This exemption applies if wholesome foods without additives are consumed, or 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 FDA or approved by the EPA or the USDA's Food Safety and Inspection Service.

3. Exemption categories 7 & 8 in the Final Rule identify specific regulatory requirements that must be met (e.g., limited IRB review, use of broad consent) as a condition of being exempt from other regulatory requirements. Since UW Oshkosh did not adopt the use of broad consent under the new rule, Exempt Categories 7 & 8 are not utilized by the UW Oshkosh IRB.
4. In order for a study to be exempt, it must fit the description of the exempt category and cannot include any non-exempt research activities.
5. Special Considerations for Vulnerable Populations and Application of Exempt Categories:
   - Exemptions may be used for research subject to Subpart B (Pregnant Women, Fetuses, and Neonates)
   - Subpart C (Prisoners) does not apply to exemptions, except when the research is aimed at involving a broader subject population that only incidentally includes prisoners.
   - Subpart D (Children) exemptions allowable for Exempt Category 1,4,5,6.
   - Limitations for Subpart D (Children):
     - Exemption Category 2 (i) and (ii) is limited to educational tests or observation of public behavior if the investigator does not participate in the activity.
       Exempt Category 2(iii) and Exempt Category 3 is not permitted for Subpart D (Children).

B. Expedited Review

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 (or a designee for IRB assignments; assignment of reviewers is currently designated to the IRB Administrator) from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
2. The expedited reviewer(s) must first determine if the study meets the definition of human subjects research and whether UWO is engaged in the research (See SOP #1: Determining if IRB Review is Required).
   - The reviewer(s) may make a determination that the project does not involve human subjects research or that UWO is not engaged in human subjects research and provide justification.
3. Criteria: To be eligible for expedited review, the proposed research must present no more than minimal risk to human subjects and involve only procedures listed in one or more of the expedited categories in the list (45 CFR.46.110).
4. The following is the HHS List of Expedited Categories of Research:
   - Expedited Category #1
     Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
     1. 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.)
     2. 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.
   - Expedited Category #2
     Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
     1. 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
     2. from other adults and children, 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.
   - Expedited Category #3
     Prospective collection of biological specimens for research purposes by noninvasive means.
     Examples:

1. hair and nail clippings in a nondisfiguring manner;
2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
3. permanent teeth if routine patient care indicates a need for extraction;
4. excreta and external secretions (including sweat);
5. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
6. placenta removed at delivery;
7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
8. 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;
9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
10. sputum collected after saline mist nebulization.

- Expedited Category #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:
  1. 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;
  2. weighing or testing sensory acuity;
  3. magnetic resonance imaging;
  4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
  5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- Expedited Category #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.)

- Expedited Category #6
  Collection of data from voice, video, digital, or image recordings made for research purposes.
- Expedited Category #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.)
- Expedited Category #8
  Continuing review of research previously approved by the convened IRB as follows:
  1. 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
  2. where no subjects have been enrolled and no additional risks have been identified; or
  3. where the remaining research activities are limited to data analysis.
- Expedited Category #9
  Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2-8 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.

5. Expedited review categories do not apply in the following instances:
   - 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.
   - The expedited review procedure may not be used for classified research involving human subjects.
6. Standard requirements for informed consent (or its waiver or alteration) apply to expedited research.
7. The expedited reviewer(s) assigned may exercise the following:
   - Approve a study as submitted
   - Request revisions (in order to secure approval)

- Refer study for full board review at a convened meeting

8. Expedited reviewers may not disapprove a study. Disapproval of a study can only be determined through vote with a quorum in a convened meeting of the full board.

C. Full Board Review

1. For non-exempt research that is not eligible for expedited review, the IRB must review proposed research at convened meetings in which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.
2. All research that is more than minimal risk is reviewed by the full board
3. IRB protocol discussion at the meeting is led by a primary reviewer. Upon request, a secondary reviewer may also be assigned.
4. The convened IRB may make the following motions:
   - Approve a study as submitted
   - Request revisions (in order to secure approval)
     - Implies that if the researcher makes the requested revisions, the protocol will be approved. The IRB reserves this motion for protocols which need specific information or changes in order to meet the criteria for approval.
     - Minor revisions may be reviewed through expedited review by the IRB Chair or their designee if the IRB agrees to the revisions being reviewed via expedited review at the convened meeting in which the revisions request was delineated. The IRB's action, along with the requested revisions must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).
     - Substantive revisions will be reviewed by the full board. If the IRB requires that the investigator make specified changes to the research protocol or informed consent document(s) and resubmit such documents to the convened IRB for subsequent review, the IRB's action, along with the basis for requiring changes must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).
   - Disapprove a study
     - Typically used after the IRB has requested substantive revisions from the researcher and the IRB determines that the study does not meet the criteria for IRB approval.
     - IRB may use this motion for the following conditions:
       i. Criteria for IRB approval are not met under 45 CFR 46.11.
       ii. When applicable, conditions for Subparts B, C, or D of 45 CFR part 46 are not met.
     - If the IRB disapproves a research activity, the IRB must include a statement of the reasons for its decision in the written notification to the investigator and the institution, and provide the investigator an opportunity to respond in person or in writing (45 CFR 46.109(d); 21 CFR 56.109(e)). The minutes must document the IRB's action

along with the basis for disapproving the research (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).
    - Exempt, Limited IRB Review, and Expedited Review methods cannot disapprove a protocol. If a reviewer determines that the criteria for IRB approval are not met, the protocol should be elevated to full board review.
- Table the study
    - IRB may use this motion if the IRB needs additional information to make a determination, additional expertise is needed, loss of quorum, or if there is insufficient time for the IRB to conduct the review.

5. The convened IRB will also make a risk determination on studies, determine the frequency of continuing review, and how continuing review will be conducted (Expedited Review vs. Full Board Review).
    - The IRB must conduct continuing review of full board research at intervals appropriate to the degree of risk, but not less frequently than once per year.
    - If the IRB determines that the risk level is minimal risk, continuing review may be conducted through Expedited Category 9.
    - If the IRB determines that risk is more than minimal risk, continuing review will be conducted by Full Board Review.

III. Communication to Researchers Regarding IRB Review and Actions:

A. The IRB will provide written notification to the researcher regarding the outcome of the review. If revisions to the protocol are requested in order to secure approval, instructions for resubmitting the proposal for review will be included in the written notification to the researcher.

IV. Researcher Responsibilities Following Approval of Study:

A. Modifications to IRB Approved Research
    1. If changes to an approved study are requested, the researcher must submit an IRB Modification Request Form and obtain IRB approval prior to implementing any changes.
    2. Modification requests to a study will be reviewed by Expedited or Full Board Review based on the changes requested.
        - Modifications which increase the level of risk or involve non-exempt research activities not included in the expedited review categories list will be referred to the full board.
    3. Updates to research personnel may be submitted using the IRB Research Personnel Change Form. Note: Change in personnel (other than Principal Investigator (PI) or Co-PI) and verification of training requirements are reviewed administratively by IRB staff.

B. Continuing Review
    1. Exempt Studies:
        - Continuing review is not required for studies determined to be Exempt by the IRB. This includes studies requiring Limited IRB Review as a condition of exemption.

- The IRB Office will send an annual status check-in email for exempt studies.

2. Non-Exempt Studies (Initial Review via Expedited or Full Board Review):
   - Per HHS, the IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects.
     - Continuing review is *usually* conducted in the manner in which the protocol was initially reviewed (expedited or full board).
     - If the convened full board determined that the risk level of a particular study was minimal risk, continuing review may be reviewed under expedited Category 9.
   - Effective on January 21, 2019, for studies reviewed under the Revised Common Rule, continuing review will no longer be required for:
     - Studies that qualify for the expedited review process, unless the reviewer requests continuing review and justifies it;
     - Studies (regardless of review path) that have completed subject intervention/interaction and the activity is limited to either final analysis of identifiable data/biospecimens
     - Accessing follow-up clinical data from procedures that subjects undergo as part of clinical care procedures
     - The IRB may request continuing review of studies in circumstances where it is not required if rationale is provided and documented.
   - Non-exempt studies that are determined by the IRB to not require continuing review will be sent an annual status check-in email from the IRB Office.
3. For existing non-exempt studies which were approved prior to January 21, 2019 and the Revised Common Rule implementation, continuing review is required at intervals appropriate to the degree of risk, but not less than once per year. If a PI wishes to transition their study to the Revised Common Rule Regulations, they may submit a request to the IRB Office. Updates to the consent process and document will be required to transition the study if the PI is still recruiting participants.
4. A Continuing Review Form must be submitted to the IRB prior to the annual anniversary date for studies requiring continuing review. The IRB will evaluate the need for further continuing review at that time and allow the PI to decide if they wish to transition the study to the Revised Common Rule Regulations.

C. Principal Investigator Reporting Requirements
   1. Adverse Events/ Unanticipated Problems: Any unanticipated problems involving risks to subjects or others or adverse events must be reported to the IRB within 72 hours of the event using the IRB Unanticipated Problem Form or an IRB Adverse Event Form.
      - The following guidance defines adverse events and unanticipated problems and indicates when the IRB would be required to report the incident to OHRP:
        OHRP Guidance: Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

2. Noncompliance with Protocol: Deviations from the protocol should be reported to the IRB within 72 hours of incident and/or discovery using the IRB Noncompliance Form.
3. Subject Complaints: Participants are provided contact information for both the IRB Office and the researcher. The researcher should notify the IRB of subject complaints which involve unanticipated problems, noncompliance, or matters in which they cannot resolve following SOP #8: Participant Concerns or Complaints.

D. IRB Study Closure:
   1. Researchers must complete an IRB Closure Form upon completion of their study (exempt and non-exempt studies).

E. IRB Records
   1. Per UWO record retention policy, IRB records must be kept for 3 years from the closure date of the study.

V. Suspension or Termination of IRB Approval for Existing Studies

IRBs are authorized to suspend or terminate approval of research not conducted in accordance with IRB requirements or where unexpected serious harm to subjects occurs.

- Urgent situations allow the IRB Chair or Institutional Official (IO) to suspend a study. A meeting with the full board will follow to determine subsequent actions.

Appendix 1: UW-Oshkosh IRB Review Process