University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 7 Effective Date: November 16, 2016 Last Reviewed/Updated: December 15, 2016 Page 1 of 5; Appendix A, B, and C Prepared By: A. Miron, K. Schill, and L. Mann	**Title:** **Student Class Assignments**

UWO supports a wide range of undergraduate, graduate, and doctoral student research projects using human subjects from course-related research exercises to dissertation studies.

I. Policy Goals:

This policy applies only to activities that involve student class assignments. Its goals are to clarify when student assignments and projects fall under the jurisdiction of the IRB and to emphasize the instructor's obligations to consider and mitigate potential risks to individuals even when the class assignments are not under IRB purview.

This policy works in conjunction with the Principal Investigator (PI) Eligibility Policy, effective July 1, 2016, sent to all University of Wisconsin Oshkosh faculty and instructors from the Provost and Vice Chancellor who serves as the Institutional Official for Research. According to that policy (SOP#6), **undergraduate and graduate students can serve only as research personnel on UW Oshkosh projects. Students are not permitted to serve as Principal Investigator.**

II. Policy Definitions:

1. **Student Class Assignments**
   For the purposes of this policy, *student class assignments* include activities that are:

   - Conducted during, or outside of class, with students enrolled in an official course (for credit or not for credit)
   - Conducted in fulfillment of class assignments involving interactions with individuals other than the members of the class
   - Typically initiated and completed within a single term
   - Designed to teach research methods through student interaction with individuals or data about individuals, or designed to help students understand concepts covered by the course
   - Generally not intended to create new knowledge or to lead to scholarly publication

   ** Please note that student projects that result in undergraduate honors theses, master's theses, or doctoral dissertations need IRB review if they are determined to be research involving human subjects. To determine if a quality improvement or quality assessment project meets the definition of human subjects research requiring IRB oversight, please complete an IRB Determination of Human Subjects Research Form for Quality Improvement/Assessment Activities.

2. **Research**

The definition of research as defined by the Department of Health and Human Services (DHHS) regulations: "Research means a *systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*." 45 CFR 46.102 (d)

To be considered a "systematic investigation", the concept of a research project must meet all of the following:

- Attempt to answer research questions.
- Is methodologically driven, that is, it collects data or information in an organized and consistent way.
- The data or information are analyzed in some way, be it quantitative or qualitative data.
- Conclusions are drawn from the results.

"Generalizable Knowledge" would include one or more of the following concepts:

- The knowledge contributes to a theoretical framework of an established body of knowledge.
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study.
- Publication, presentation or other distribution of the results is intended to inform the field of study.
- The results are expected to be generalized to a larger population beyond the site of data collection or population studied.
- The results are intended to be replicated in other settings.

III. When do student class assignments NOT require IRB review?

Student class assignments, as a general rule, are not systematic data collection efforts intended to develop or contribute to generalizable knowledge and, thus, do not meet the federal regulatory definition of research. Therefore, as a general rule, student class assignments do not fall under the jurisdiction of the IRB and do not require IRB application, approval, or oversight. See Appendix A: Classroom Research Project Checklist for IRB Exclusion.

IRB review is not required for research projects conducted ***solely*** to fulfill course requirements and the results of the classroom assignment are ***only*** used and shared as follows:

- In the classroom, department, or a local UWO setting, designed to exhibit coursework or to continue the learning process related to presentations; and/or,
- If the project involves gathering data from or about a company, agency, or organization, and the data/results are shared only with the company, agency, or organization for internal purposes

***However, if* data will be shared *beyond* the circumstances described above then the project must receive IRB approval prior to initiation.** (e.g., Publication, presentation or other distribution of the results intended to inform the field of study). If the results

are expected to be generalized to a larger population beyond the site of data collection, population studied, or intended to be replicated in other settings, then IRB approval is required.

EXAMPLE 1: Does this type of project need IRB review? CLASS PROJECTS or PRACTICA that involve direct interaction with human subjects (e.g., in person, via mail, email, web surveys, or telephone), but where the purpose is training, an educational exercise or professional development, and not research. The project or practicum is not "research" even if students ask people questions as part of learning how to conduct interviews or surveys, take oral histories, administer assessments, or perform "in-house" evaluations as requested by the practicum site. **No IRB action required (neither approval nor determination of human research status) but a determination may be requested from the IRB if an instructor or students are unsure, or if documentation is required by gatekeepers (e.g., schools, businesses, agency) for access to participants.**

EXAMPLE 2: Is IRB approval required in order for students to present at Celebration of Scholarship? If the project meets the federal definition of research (see Section II.2. Research), then IRB approval is required in order for the students to present at Celebration of Scholarship. If the class project is conducted solely to fulfill course requirements and the results are presented in a local UWO setting only (e.g., Celebration of Scholarship) as a display of coursework and to enhance the student's learning experience, then IRB approval is not required. The course instructor is responsible for the ethical review and oversight of the projects considered non-research. An IRB Determination of Research Form may be submitted to the IRB office if documentation of a determination from the IRB is requested in order to present results at Celebration of Scholarship.

IV. When do student class assignments require IRB review?

IRB approval is required when a project meets the federal definition of human subjects research 45 CFR 46.102. A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual; or 2) identifiable private information. Student class assignments that are intended to collect information systematically with the intent to develop or contribute to generalizable knowledge meet the federal regulatory definition of "research." These class assignments fall under the jurisdiction of the IRB and require IRB application, approval and oversight. Instructors wishing to use such assignments for research purposes must apply to the IRB and obtain approval of these assignments before they begin.

EXAMPLE 1: Does the Instructor submit a single IRB application or does each student need to submit individual IRB applications for class assignments?
If students within a course are all following the same research protocol, a single IRB Application Form may be submitted by the Instructor. For students within a course conducting individual research projects that will have varying research questions and methods, a single IRB Course Umbrella Protocol Form may be submitted by the Instructor. The course umbrella protocol form must include a course protocol checklist

for each individual student project along with requested appendices for each individual project. Projects covered under a course umbrella protocol must meet the following criteria outlined in the course protocol checklist:

- be no more than minimal risk and fall under an Exempt (Appendix B) or Expedited (Appendix C) category of human subjects research
- not involve any protected or vulnerable populations
- not involve deception
- not ask questions which are sensitive in nature

The Instructor or the IRB may request that a student research project that does not meet the required criteria on the checklist, submit a standard IRB Protocol Application for the IRB to review. The class instructor and the students must complete human subjects research ethics training through CITI Program prior to conducting research with human subjects.

EXAMPLE 2: Do independent research projects (e.g., thesis, honor projects, independent studies) require IRB review? Independent research projects conducted by students that collect data through interaction or intervention with living people or access identifiable private information fall under the jurisdiction of the IRB. A standard IRB Application to the IRB for these student research projects must be submitted by a faculty member who will mentor the student and serve as the Principal Investigator.

EXAMPLE 3: Does data collected for class assignments require IRB review, if the instructor or student decides after the project is completed that they would like to use the data for research purposes? Class assignments may become regulated human subjects research if the faculty member or the students change their plans to use the data during the data collection or after the data have been collected. For example, if a student decides after the completion of a class project or practicum activity to pursue additional activities with data containing direct or indirect identifiers for research purposes, then an IRB Existing Data Application would need to be submitted for permission to use the data collected for research purposes.

EXAMPLE 4: Does a class project involving educational experience and research require IRB review? CLASS PROJECTS or PRACTICA that involve direct interaction or secondary analyses of private identifiable data that are undertaken as both an educational experience and as research (e.g., the research design follows a systematic design and results of these activities will be disseminated outside of the classroom to contribute to generalizable knowledge and inform the field of study) require IRB review.

V. Instructor Responsibility

Even when a class assignment is "non-research" and, thus, not under the jurisdiction of the IRB, faculty members have an obligation to ensure that students understand their ethical obligations in carrying out their assignments. Instructors should provide guidance to students collecting information so as to minimize any unwitting or unintentional risk to other students or to individuals, especially if students will interact with or collect private information about vulnerable individuals or protected populations. These risks may include: physical harm, or potential psychological, social, economic, or legal

harm, especially when data is collected about sexual activity, use of alcohol or illegal drugs, or involvement in illegal activities. Such risks can be exacerbated when the individuals outside the classroom are minors, pregnant women, prisoners, or people who are otherwise vulnerable, such as cognitively impaired persons or others with diminished consent capacity.

The class instructor is responsible for ensuring that appropriate administrative permission is obtained to conduct class assignments at off-site locations (e.g., interviewing employees at a company or distributing a survey to students in a local school).

Even if the project stays within the class and IRB review is not required, the instructor of the class should be aware of the types of questions being asked and all ethical principles regarding teaching and their discipline should be followed in addition to the ethical standards regarding privacy and confidentiality.

Faculty members may use a number of ways to educate students and encourage responsible interactions with others, including:

- Reviewing students' plans for classroom or group projects and suggesting improvements in design and protections for confidentiality. The IRB application forms, consent templates, reviewer checklists, etc. may be used internally for the class instructor or department to conduct an ethical review.
- Requesting that students take the CITI training tutorial on human subject protection before collecting information from others;

  Please see http://www.uwosh.edu/grants/support/responsibilities-compliance/human-research-protection-program-and-IRB for CITI training requirements and instructions.

- Explaining ways in which students should be attentive to the welfare of individuals in cases in which:
  - Vulnerable populations, such as minor children, prisoners, cognitively impaired individuals, or those without capacity to provide consent.
  - Any possibility of physical harm to the student or other individuals
  - Students will ask sensitive questions including topics related to sexual activity, victimization, use of alcohol or illegal drugs, or involvement in illegal activity
- Requiring printed instructions/information on questionnaires that explain the use of the data for coursework and include the name and contact number of the instructor
- Requiring, whenever possible, anonymous data collection so that the data are not linked to individuals
- Requiring that information identifying individuals be kept separately from the information collected from those individuals
- Requiring destruction of non-research data at the end of the course or within a short time afterward
- Instructing students about the privacy and security vulnerabilities associated with networked computers and technology devices

Appendix A: Classroom Research Project Checklist for IRB Exclusion

This document is intended to provide guidance to UWO instructors in assessing whether classroom projects may be excluded from IRB review and approval by the UWO Institutional Review Board (IRB). All items below must be satisfied for classroom projects to proceed outside of IRB review. This checklist is simply a reference and does not need to be submitted to the IRB. If you have questions or are uncertain if IRB review is required, please contact the IRB chair or irb@uwosh.edu.

☐ The research project is to be performed by students enrolled in a graduate or undergraduate course at UWO and is a requirement for completion of the course.

☐ The overriding and primary purpose of the project is providing a learning experience in the methods and procedures of research or for quality improvement or quality assessment activities.

☐ The advisor is aware of all aspects of the research project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.

☐ There is no intent to produce generalizable knowledge or to disseminate the findings beyond presentation to instructors or peers in a UWO classroom setting or local campus venue, departmental or interdepartmental seminars, or beyond a company or organization if you were collecting data specifically for them for internal purposes.

☐ Appropriate administrative permission has been obtained to conduct any off-campus projects.

☐ The project involves no more than minimal risk to subjects (i.e., when "the risks of harm anticipated in the proposed research are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests").

☐ The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed.

☐ The project involves the voluntary participation of individuals without any coercion or pressure being placed upon them. The instructor/students have considered whether a consent document should be provided to participants.

*If documentation is required determining whether IRB review is required, please complete the IRB Determination of Human Subjects Research Form.

References

- http://research-compliance.umich.edu/human-subjects/human-research-protection-program-hrpp/hrpp-policies/class-assignments-irb-approval
- http://orip.syr.edu/human-research/policy-for-student-projects/policy-for-student-projects.html
- http://www.uab.edu/research/administration/offices/IRB/Documents/IRB%20Guidance%20for%20Student%20Research%20and%20Class%20Projects.pdf
- https://vpr.tamu.edu/compliance/rcc/irb/irb-guidance/classroom-guidance-and-checklist
- https//hrpp.msu.edu/definitions-generalizable-knowledge

Appendix B: Checklist for Determination of Exemption

☐ **Exempt Category #1**

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Note: This category may be applied to research involving children.

☐ **Exempt Category #2**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: Surveys on sensitive or personal topics which may cause stress to study participants are not exempt from IRB review. This category may apply to research with children only when the investigator observes public behavior but does not participate in that behavior or activity. This section is not applicable to survey or interview research involving children.

☐ **Exempt Category #3**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:

- The human subjects are elected or appointed public officials or candidates for public office.
- Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ **Exempt Category #4**

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- **Examples:** Existing Data, Records Review, Pathological Specimens

Note: Inclusion of fetal tissue in the pathological specimens category is prohibited by regulation and requires IRB review.

☐ **Exempt Category #5 NOTE:** This Category is NOT available to individuals.

Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs
- Possible changes in or alternatives to those programs or procedures
- Possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Exempt Category #6**

Taste and food quality evaluation and consumer acceptance studies.

- If wholesome foods without additives are consumed
- 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.

Note: This category may be applied to research involving children; however, institutional policy requires written parental consent to include children in taste testing or odor studies.

Appendix C: Checklist for Determination of Eligibility for Expedited Review

Mandatory Criterion:

Unless otherwise exempt, project must be reviewed by the full IRB if this criterion is not met.

☒	**The proposed project meets the definition of human subjects research and presents no more than minimal risk to human subjects. If it does not meet this criterion, then Full Board Review.**

Additional Criteria:

To be eligible for expedited review the proposed research must meet **at least one** of the categories below, **and** involve no procedures not included in this list (45 CFR.46.110). Indicate below all categories that apply to the proposed research. NOTE: Inclusion on this list is not sufficient to deem an activity to be of minimal risk

☐ **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.

Applicability of the Expedited Categories:
Expedited review procedures can be considered when research activities:

1. present no more than minimal risk to human subjects, and
2. involve only procedures listed in one or more of the nine categories.

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.

The categories 1-7 apply regardless of the age of subjects, except as noted.
Researchers are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) also apply to expedited review.

When Expedited Review Categories do not apply

- 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.