

**University of Wisconsin-Oshkosh  
Institutional Review Board (IRB)**

**STANDARD OPERATING PROCEDURES (SOP)**

<b>SOP Number: 7</b> Effective Date: November 16, 2016 Updated: April 3, 2019 Last Reviewed: April 3, 2019 Page 1 of 6; Appendix A Prepared By: A. Miron, K. Schill	<b>Title:</b>  <b>Student Class Assignments</b>
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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. Goal:**

**This Standard Operating Procedures 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 a [Determination of Human Subjects Research Form](#).

## 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 in most cases. Therefore, most student class assignments do not require IRB review or oversight. See Appendix A: Classroom Research Project Checklist for Exclusion from IRB Review.

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 of Human Subjects Research](#) may be requested from the IRB if an instructor or student is unsure, or if documentation is required by gatekeepers (e.g., schools, businesses, or agency) for access to participants.**

**EXAMPLE 2: Is IRB approval required in order for students to present at Celebration of Scholarship?** It depends. 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. Undergraduate honors theses, master’s theses, or doctoral theses all require IRB review and approval for human subjects research. 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 all projects considered non-research. A [Determination of Human Subjects 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 a living individual about whom an investigator is conducting research:** (1) Researcher obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Researcher obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (See SOP #1 for definitions of these terms).

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 or Expedited category of human subjects research (See [SOP # 2: IRB Application and Review Process](#))
- 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.

**EXAMPLE 5: Is IRB approval required in order for students to present projects involving human subjects at Posters on Rotunda, NCUR conference, or publish in Oshkosh Scholar?** IRB review and approval is required for these scenarios when working with human subjects since the presentation or distribution of the results are intended to inform the field of study and are expected to be generalized to a larger population beyond the site of data collection or population studied. Students should note their IRB approval when presenting outside of UWO or publishing human subjects data.

## 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.
- Requiring students take the CITI training tutorial on human subject protection before collecting information from others;

Please see <https://uwosh.edu/sponsoredprograms/irb/training/> for CITI Program training requirements and instructions.

- Explaining ways in which students should be attentive to the welfare of individuals and avoid the following:
  - Vulnerable populations, such as minor children, prisoners, cognitively impaired individuals, or those without capacity to provide consent.

- o Any possibility of physical harm to the student or other individuals
- o Asking 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

## 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 A: Classroom Research Project Checklist for Exclusion from IRB Review**

This document is intended to provide guidance to UWO instructors in assessing whether classroom projects involving human subjects may be excluded from 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](mailto:irb@uwosh.edu)

### **All items below must be satisfied for classroom projects to proceed outside of IRB review:**

- 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 your subjects' daily life or during the performance of routine physical or psychological examinations or tests").
- 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 instructor 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 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 and/or legal guardian or legally authorized representative.

\*If documentation is required determining whether IRB review is required, please complete the [IRB Determination of Human Subjects Research Form](#).

**Important Note:** If a student project includes surveying minor students, the project should be submitted to the IRB for review (see SOP #3 for more information). The Protection of Pupil Rights Amendment (PPRA) is a federal law that affords certain rights to parents of minor students with regard to survey questions. The PPRA applies to any "local educational agency" that receives funding from the U.S. Department of Education (DOE). A "local educational agency" includes any elementary schools, secondary schools, school district, or local board of education which are recipients of funds from DOE. PPRA lists eight categories of protected information/sensitive questions:

1. Political affiliations of student or student's parent;
2. Mental or psychological problems of student or student's family;
3. Sex behavior or attitudes;
4. Illegal, anti-social, self-incriminating or demeaning behavior;
5. Critical appraisals of others with whom students have close family relationships;
6. Legally recognized privileged or analogous relationships;
7. Religious practices, affiliations or beliefs of student or student's parent;
8. Income