



Ver. # 1.1 Effective Date: Sep 2 2015 Last updated: Aug 24 2021	<b>IRB Review of Class Research                  Projects</b>	Supersedes Previous Ver.: <b>Yes</b>
---	---	---

## I. Policy Statement

It is the policy of Ball State University’s IRB that all research be conducted in accordance with the tenets of the *Belmont Report*. This includes maintaining the highest ethical standards and full respect for persons participating in human subjects research (HSR).

Class Research Projects designed to educate and train students in research methodologies and techniques should follow the same guiding principles as if they were HSR protocols. These projects, however, may not require IRB review and approval.

## II. Operational Definition(s)

**Class-based Research:** Any research project whose primary purpose is to train and educate students in research methodologies, research design, research techniques, etc. and is part of an approved course. These types of research projects are intended to remain within the classroom setting and/or within the learning parameters of the course.

## III. Procedures

1. Any class-based research project that meets the applicable definition will not be reviewed by the IRB (See important exceptions in item 4-6 below). Instructors are solely responsible for ensuring all class-based research is conducted ethically, is scientifically sound, and is in-line with applicable practices of HSR protections (e.g., using an informed consent process).
  - a. For purposes of this policy, class-based research projects that have some form of local dissemination, such as a poster presentation on campus or during a departmental event, does not constitute “dissemination” and/or “generalizable knowledge” for purposes of applying 45 CFR 46.
  - b. Class-based research projects that students plan to submit for publication to a scholarly journal or presentation at a conference may constitute “dissemination” and/or “generalizable knowledge” and will be reviewed by the IRB on a case-by-case basis. If the course instructor believes publication/presentation is likely, then these types of projects should be submitted to the IRB for an initial determination as to whether formal IRB review is needed. Justification regarding the likelihood of dissemination should be provided by the course instructor.
2. For purposes of this policy, any HSR conducted as part of a dissertation, thesis, or for scholarly publication are outside the scope of class-based research and will require IRB review.
3. Any class-based research projects that represent preliminary investigation for thesis or dissertation do not necessarily require IRB review.
  - a. A preliminary investigation is designed to explore the feasibility of the study, refine data collection procedures and instruments, or prepare a better, more precise research design. Such a study would not contribute to generalizable knowledge and therefore is not considered research, and may not require IRB review.

- b. If either the instructor or students consider using the data from preliminary investigation for thesis or dissertation, the research must be submitted for IRB review prior to collect data.  
**Note:** The preliminary data collected from a non-IRB approved project cannot be used as research data for the IRB-approved project.
4. Any class-based research project that will potentially place human participants at greater than minimal risk (ex. use of identifiable information and illegal behaviors) must be submitted and reviewed by the IRB regardless if it meets the definition of class-based research.
5. Any class-based research project that will potentially recruit protected populations (e.g., children under age 18, prisoners, persons who are cognitively impaired, etc.) must be submitted and reviewed by the IRB regardless if it meets the definition of class-based research.
6. Class-based research that involves information/data governed under any other regulations (ex. HIPAA, FERPA) must still comply with these regulatory and/or policy requirements even if IRB review is not conducted. Failure to do so may constitute a violation under the applicable regulation/statute.
  - a. If a FERPA Officer or a HIPAA Privacy Officer request formal IRB review before releasing any protected information, the researcher must submit the project for IRB review.
  - b. The instructor or the student researcher must contact the applicable FERPA or HIPAA Privacy Officer before engaging in any activity that involves FERPA or HIPAA protected information.
7. Students are not allowed to serve as a PI of record in IRB applications. Thus, the course instructor or the faculty advisor should be listed as the PI of record when IRB review is required.

#### **IV. Responsibility of the Course Instructor**

1. It is the responsibility of the course instructor to oversee the ethical conduct of research, to ensure the protection of human subjects (including verifying a process is in place for obtaining voluntary informed consent from research subjects when appropriate), to instruct the preparation of the IRB application, and to monitor the students' progress.
2. When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should:
  - a. Understand the elements of informed consent;
  - b. Develop appropriate consent documents or processes;
  - c. Plan appropriate strategies for recruiting subjects;
  - d. Identify and minimize potential risks to subjects;
  - e. Establish and maintain strict guidelines for protecting privacy and confidentiality, and
  - f. Allow sufficient time for IRB review (if necessary) and completion of the project.
3. Course instructors may submit a summary sheet with all of the potential projects to the ORI Human Research Protection Program (HRPP) Manager for initial review and determinations at the beginning of the course. Those projects determined as potential HSR will then be submitted for review.
4. Course instructors may provide sufficient justifications and supporting materials. For example, to document the likely dissemination of a class project, the course instructor may provide the specific conference name or journal title to which the project may be submitted.
5. If a study is more than minimal risk, or if an instructor is unclear on the appropriateness of IRB review, the instructor may consult with the Office of Research Integrity and/or the Chairperson of the IRB regarding the need for, and appropriateness of, class-based research project review by the IRB.
6. If IRB review is required for a class research project, the instructor should serve as a PI of record for the project.

## **V. Alternative Review Options**

While the IRB will not review class-based research projects, instructors have various options available to them for having these projects reviewed. These include, but are not limited to:

- a. Having the instructor review the proposed research;
- b. Utilizing a mock-IRB forum;
- c. Coordinating a class question and answer session with Office of Research Integrity staff; or
- d. Other options that may become available over time.