

## Institutional Review Board & Human Subjects Office

### Course-Related Student Project Policy and Procedures 5/2/19

#### Introduction

When students conduct research as a course assignment, for educational purposes, there are some conditions under which IRB approval may not be required. Course-related student projects are usually limited in scope and designed to teach students how to conduct research. They typically are not intended to further scientific knowledge in a particular field of study or to lead to scholarly publication, including a thesis or dissertation. The Policy on Course-Related Student Projects & Human Subjects Research in the [IRB Standard Operating Procedures and Researcher Guide](#) (Section I, Part 12.D) outlines the basis for why these projects do not meet the [regulatory definition of human subjects research](#) and therefore do not require IRB approval. The policy also specifies the information students must disclose to potential subjects even when the project does not require IRB approval.

#### Course-Related Student Project Checklist

The IRB provides a [Course-Related Student Project Checklist](#) to assist instructors and student researchers in determining whether the project can be conducted without IRB approval. Based on the responses to the questions in the checklist, students may be instructed to submit a [Human Subjects Research Determination \(HSRD\) form](#) in the eResearch application system ([HawkIRB](#)) to ask if IRB approval is necessary. Student researchers should submit the form along with a project proposal to the instructor for review prior to the start of the project. Instructors should review the student proposal and the completed checklist and determine if IRB review may be necessary.

#### Course Instructor Responsibilities

The course instructor is authorized to decide whether the project meets the requirements for a Course-Related Student Project. We strongly encourage instructors who assign course-related research projects to use the [Course-Related Student Project Checklist](#) and consult with the [IRB Education & Outreach Program](#) prior to the beginning of the semester to make sure the groundwork is laid for student projects to comply with all applicable federal human subjects regulations and University of Iowa policies.

The course instructor should:

1. Review student research plans prior to subject recruitment and data collection.

2. Use the [Checklist for Course-Related Student Projects](#) to determine if IRB approval may be required. (You may need to download to your desktop for full functionality) The Checklist collects information about study design and procedures to help the course instructor determine if the project can be conducted without IRB oversight or if the student researcher should consult with the IRB about whether approval is required.
3. Review any revisions to the students' projects to ensure they meet the criteria for course-related student projects.
4. Ensure that classroom assignments are carried out with due consideration of the UI ethical and legal responsibility to protect individuals who participate in these activities.
5. Determine if a classroom project warrants enhanced oversight. Instructors may determine a project warrants enhanced oversight when:
  - a. There is a potential physical, psychological, social, economic, or legal risk to participants, or
  - b. The project involves vulnerable populations, such as cognitively impaired individuals, or
  - c. Students have a supervisory role in their work life over the people they want to recruit for their classroom project.
6. Educate students about the potential for harm, as listed above, and take all possible steps to eliminate risks to these individuals.
7. Provide guidance and oversight about the use of data collected in a classroom project, in a manner consistent with UI policy.
8. Assume responsibility in the event of a breach of confidentiality involving data collected for the project, or if data are released outside the parameters of this policy.
9. Address all complaints regarding course-related student projects.
10. Ensure that student researchers provide the following information to participants (See Student Responsibility, below)
11. Carefully consider whether students are qualified to adequately safeguard the rights and welfare of research subjects. ([UI Ops Manual, Section II, Ch. 27.4](#))

### [Student Responsibilities for Course-Related Projects](#)

Students who conduct research as a course requirement, without IRB approval, must comply with the policy regarding this type of research. That includes consulting with the course instructor about whether IRB approval would be required. The results of a course-related student project may not be used for a thesis or dissertation project. If the results indicate the need for further research, the student researcher should obtain IRB approval to conduct the project outside the context of a class project.

Student researchers should conduct the project exactly as described in the [Course-Related Student Project Checklist](#). If the project design changes, complete a new Checklist and consult with the course instructor about whether IRB approval may be required.

Provide potential subjects with the following information:

- Student name and the name of the course.
- Course instructor name and contact information
- Who will have access to the individual data or summarized results (e.g. instructor, members of a group project team, the whole class, an outside company/organization/agency)
- Participation is voluntary; they may stop participating at any time.