

Carnegie Mellon University

Course-Related Student Project Guidance

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Introduction

All activities meeting the federal definitions of Human Subjects Research that are carried out at Carnegie Mellon University (CMU) or under its auspices must be reviewed and approved by an Institutional Review Board (IRB) prior to the start of the research.

This Guidance applies to undergraduate and/or graduate students conducting course-related projects at CMU and faculty members or instructors who supervise course-related student projects. 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 or other vocation-related activities. The course-related projects typically are not intended to further scientific knowledge in a particular field of study, suggest generalizable results, or to lead to scholarly publication, including a thesis or dissertation. This Guidance outlines the basis for when these course-related projects do not meet the regulatory definition of Human Subjects Research and therefore do not require IRB approval. This Guidance also specifies the information students must disclose to potential participants even when the course-related project does not require IRB approval.

When IRB Review and Approval is Not Necessary

IRB approval is not required if the course-related student project meets **ALL** of the following criteria:

1. The purpose of the assignment or activity is to teach research methodology or other vocation-related activities.
2. The results of the assignment do not develop or contribute to generalizable knowledge because the activities are course assignments/projects conducted by a student only to satisfy the curriculum requirements of a course, AND the results of the project do not at any time leave Carnegie Mellon University accompanied by a suggestion that the results are generalizable.

3. The project's involvement of human subjects is limited to surveys, questionnaires, interview procedures, observation of public behavior, benign behavioral interventions, or standard educational exercises.
4. The project does not include prisoners, children, or their data.
5. The information is recorded by the researcher without any direct or indirect identifiers linking anyone to his/her data, OR, if direct identifiers are used when recording the data, the information gathered could not reasonably harm a person's reputation, employability, financial standing, or place a person at risk of criminal or civil liability.
6. The project is not conducted or supported by a [federal department or agency that has adopted the Common Rule](#) (e.g., NIH, NSF, DoD, etc.) (45 CFR 46 subpart A).

NOTE: Honor's, Master's, and Doctoral thesis and dissertation projects that involve research with human subjects always require IRB review and approval.

Course-Related Student Project Checklist

The IRB provides a "Course-Related Student Project Checklist" to assist course instructors and student researchers in determining whether a project can be conducted without IRB approval. Student researchers should submit the Checklist along with a project proposal to the instructor for review and certification prior to the start of the project. Based on the responses to the questions in the Checklist, students may be directed to submit an application in SPARCS for either IRB approval of the project, a Not Human Subjects Research determination, or a Not Research determination. A copy of the completed Checklist should be submitted in SPARCS along with the application.

Instructors should review the student proposal and the completed Checklist and determine if IRB review may be necessary. If the Checklist indicates an IRB application is required, the instructor should ensure that the project is reviewed by the IRB and either approved or a Not Research/Not Human Subjects Research determination is given prior to the involvement of Human Subjects in the project.

Course Instructor Responsibilities

The course instructor is responsible for determining 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 as soon as possible to make sure the groundwork is laid for student projects to comply with all applicable federal human subjects regulations and Carnegie Mellon

University 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. 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 submit an application to the IRB. The instructor is responsible for ensuring appropriate approval is obtained prior to the start of the project, if 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 CMU 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.
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 Guidance or any signed agreements.
9. Address all complaints regarding course-related student projects.
10. Ensure that student researchers provide the appropriate information to participants (See Student Responsibilities below)
11. Carefully consider whether students are qualified to adequately safeguard the rights and welfare of research subjects.

Student Responsibilities for Course-Related Projects

Students who conduct research as a course requirement, without IRB approval, must comply

with this guidance 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 without IRB approval. 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.

If the student(s) will publish or present the research results outside of the CMU community or the course sponsor (if any) and the publication/presentation suggests that the information is generalizable/applicable to others, IRB approval for the research or a Not Human Subjects Research Determination from the IRB must first be obtained. Publication and presentation may include conference presentations, poster presentations, peer-reviewed journals, and public websites.

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.

If data for a Course-Related Student Project will be collected through interaction or intervention with subjects, the students must provide potential subjects of the project 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