Calvin University Institutional Review Board (IRB)

Guidelines for Class Assignments and Course-based Research

The Calvin University Institutional Review Board (IRB) provides the following guidance for class activities and assignments that involve questionnaires, interviews, data-analysis, or other interactions with human subjects. "Interactions with human subjects" include interactions with a.) living individuals or b.) identifiable private information about living individuals.

If your class assignment does not involve human subjects, you do not need to secure approval from the IRB.

If your class assignment *does* involve human subjects, you must next determine:

- a.) If the assignment qualifies as research. If so, your research must be reviewed by the IRB to ensure the protection of human subjects. If not, you do not need to secure approval from the IRB.
- b.) If your research is best proposed as "standard" research involving students as co-investigators (File Form A only) or as *Course-based research* (File Form A and Form B).

Federal Definition of Research

Research is defined as systematic data collection efforts intended to develop or contribute to generalizable knowledge (e.g., publish or disseminate data *beyond* the class audience).

If any dissemination is planned (e.g., an article, a report to an agency, a poster presentation to any audience outside the class) then you must secure IRB approval prior to announcing the class activity. The IRB cannot grant retrospective approval for instructors to disseminate results from data collected as a class assignment. Please think in advance whether there is any chance you might want to disseminate data collected in conjunction with a class assignment.

If neither you nor your students will disseminate beyond the class audience, your class activities do not meet the <u>federal regulatory definition of human subjects research</u> (link is external). Your class activities do not fall under the jurisdiction of the IRB and do not require IRB application, approval, or oversight.

Of course, harm can still occur. When activities involving human subjects are not overseen by the IRB, instructors themselves must take special care to ensure that students realize the potential for harm and take all possible steps to eliminate the risks to individuals, inside and outside the class, involved in the assignment. These risks may include: physical harm, or potential psychological, social, economic, or legal harm, especially when data are 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 individuals with disabilities. Faculty members have an affirmative obligation to ensure that students understand their ethical obligations in carrying out class activities. Instructors should provide guidance to students collecting information so as to minimize any unwitting or unintentional harms to other students or to individuals, especially if students will interact with or collect private information about vulnerable individuals. In general, the IRB strongly recommends that instructors de-identity all data before making data available to students.

Course-based Research (as defined by the Calvin IRB)

Students at Calvin are involved in many categories of research involving human subjects. Some students are involved in faculty research that is not connected to a specific course. Some students are enrolled in independent studies or upper-level research courses where individuals or small groups of students conduct their "own" research under the supervision of a faculty member. In these situations, the supervising faculty must list each student as a co-investigator in the research proposal.

There are also situations where many students are involved in research that faculty intend for dissemination, but the student themselves have little "ownership" of the project. For example, 20 students might complete the same assignment, collecting data for faculty to compile and publish. In such cases, the IRB recognizes that it may be impractical to list all students as co-investigators, particularly when an instructor must receive approval in advance to design the course around a project, and students might not add into the class until a week after the semester starts. For these situations, the IRB has delineated a special category of research called *Course-based research*, wherein faculty can agree to ensure that all students in the class complete CITI Human Subjects training and abide by CITI principles for the protection of human subjects.

For the purposes of IRB proposals, *Course-based research* is defined as research that is:

- 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 (typically, but not always, the same assignments for all students)
- Typically initiated and completed within a single semester
- 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
- Involving limited or no "ownership" on the part the students (e.g., students do not help plan the project; students will NOT be credited with authorship on any product disseminated outside the class for which data were collected).
- Involving *more* than four students on a single project.
- Intended for dissemination

Investigators can request that their project be designated *Course-based research* by submitting Proposal Form B (in conjunction with Form A).

Decision Flow Chart for Class Assignments and Course-based Research

Does the assignment involve interactions with living individuals or *identifiable* private information about living individuals?



You do not need to secure approval from the IRB because your assignment does not involve Humans Subjects.



Will there be any dissemination of results beyond the professor of the course or class audience (e.g., report to an agency, poster presented to the department, published paper)



You do not need to secure IRB approval because your assignment will not contribute to generalizable knowledge and does not constitute research.



Will students have any "ownership" of the project (e.g., planning, presentation, authorship)?



Will there be more than four students involved with one project at the same time?



You must secure IRB approval. You may request that your project be designated "Course-based research" by filing Form B in addition to Form A.



You must secure IRB approval; students must be listed as co-investigators on Form A.



You must secure IRB approval; students must be listed as co-investigators on Form A.