



## **CCSU POLICY on CLASS RESEARCH ASSIGNMENTS and IRB REVIEW**

Consistent with our teaching mission, CCSU encourages a variety of classroom activities in our courses. Some instructors design class activities and assignments that involve methods commonly used in human subjects research. These activities might include (but are not limited to) interactions with people using interviews, questionnaires, or behavioral interventions. In these cases, faculty should consider whether such assignments should be reviewed by the Institutional Review Board (IRB).

### **Student Class Research Assignment Definition**

For the purposes of this policy *student class research assignments include activities that are:*

- Conducted during, or outside of class, by students enrolled in a course offered at CCSU.
- Conducted in fulfillment of class assignments involving interactions with a) members of that class or b) individuals other than the members of a class.
- The interactions with people involved in these assignments are typically initiated and completed within a single semester.
- The assignments are designed to teach research methods through student interaction with individuals or data about individuals, and/or they are designed to help students understand concepts covered by the course.
- The assignments are generally not intended to create new knowledge or to lead to scholarly presentation or publication.

Student class research assignments may or may not meet the federal definition of human subjects research. If a course includes activities that meet the above definition of student class research assignments, a determination must be made as to whether or not this activity is considered to be human subjects research that would be subject to IRB review.

### **Not Human Subjects Research (NHSR) – Class assignments NOT subject to 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.** Therefore, typically, student class assignments do not fall under the jurisdiction of the IRB and do not require an IRB application, IRB approval, or IRB oversight. However, instructors are responsible for ensuring that students conduct their research in accordance with ethical guidelines, as outlined in the *Instructor Obligation* section below.

### **Human Subjects Research (HSR) - Class assignments that ARE subject to IRB review**

Student class assignments that are intended to collect information systematically about living individuals with the intent to develop or contribute to generalizable knowledge (e.g., publish, present at professional conference or disseminate data) do meet the federal regulatory definition of "human subjects research" (HSR). These class assignments fall under the jurisdiction of the IRB and require an

IRB application, approval and oversight. Instructors supervising students wishing to use such assignments for the purpose of developing or contributing to generalizable knowledge should apply to the IRB for review and approval of these assignments *before they begin*.

Alternatively, class assignments may become subject to this policy (and be considered regulated HSR) if the faculty member or the students change their plans to use the data after the data have been collected. That is, if the faculty member or students wish to use data collected from class assignments for developing or contributing to generalizable knowledge and those data were not originally collected with such intent, they would be required to submit an application to the IRB for permission to use the data for a secondary data analysis study. The application would be subject to normal IRB review processes.

For a study to be considered for review by the IRB as a secondary data analysis, the PI must not have had any involvement in the prior data collection and/or the data must have been originally collected for a purpose other than contributing to generalizable knowledge. For proposed research to be considered as a secondary data analysis, the researcher(s) must request to use data that is “on the shelf” at the time the IRB protocol is being developed. A secondary data analysis review cannot be conducted for an ongoing research study.

Because the IRB cannot retroactively approve studies, and because not all studies will meet the ethical requirements for approval as a secondary data analysis, it is recommended that researchers seek IRB approval prior to the start of any research activities if a study is designed to serve a dual purpose, such as contributing to both institutional research and generalizable knowledge.

Independent research projects (e.g., graduate and undergraduate theses or capstones, honors’ projects, independent studies) conducted by students that collect data through interactions with living individuals or access to private information about living individuals are considered HSR and fall under the jurisdiction of the IRB. An application to the IRB for these student research projects must be prepared with the student and a faculty advisor, and must be submitted to the IRB by a faculty member. Independent research projects are not considered to be class assignments.

### **IRB Review and Process**

If an instructor determines that a student class research assignment meets the federal definition of human subjects research, then this project must be submitted to the IRB. In reviewing an IRB application for student research with human subjects conducted within the context of a course, the IRB may determine that the activity qualifies as:

- **Exempt**

An exempt determination means that the IRB has determined that the proposed research falls into one of the following established federal exemption categories: ([https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1104](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104))

A declaration of exemption means that, so long as there are no major changes in the research, its conduct does not need to be overseen on a continuing basis by the IRB. It does not mean, however, that students should act any less professionally or be any less respectful of individuals with whom they interact or about whom they collect private information.

- **Expedited Review**

Such a determination means that, based on the risk level of the research, the IRB chair, IRB

Administrator, or other designated reviewer from the membership of the IRB may approve a project on behalf of the entire IRB. If such an application is well formulated and contains all the information required by the IRB, approval times will be shorter than for projects that require revisions prior to approval. Under the federal regulations, expediting reviewers may not disapprove a project, but they may require the project be reviewed at a convened meeting of the full IRB. The IRB Administrative

Team and/or other designated reviewers will determine whether or not research submitted to the IRB requires full committee review.

#### • Full Review

Such a determination means that the IRB Chair, IRB Administrator or other designated reviewer has determined that, based on the risk level of the research, the research is neither exempt nor can it be approved by expedited review, therefore requiring review at a convened meeting of the full IRB.

#### Instructor Obligation (Regardless of HSR/NHSR Status)

Even when a class assignment is not human subjects research (NHSR according to federal regulations) and, thus, is not under the jurisdiction of the IRB, faculty members have an affirmative and ongoing obligation to ensure that students understand their ethical obligations in carrying out their assignments. Student class assignments might pose little or no risk to students or others. However, instructors should take special care to ensure that students realize the potential for harm and take all reasonable steps to eliminate the risks to students or individuals outside the class involved in the assignment. These risks may include: physical harm, or potential psychological, social, economic, or legal harm, especially when data is collected about potentially sensitive topics such as sexual activity, or topics with potential legal issues involved, such as use of alcohol or illegal drugs, or involvement in illegal activities. Such risks can be exacerbated when the individuals outside the classroom are minors, prisoners, probationers, parolees, or people who are otherwise vulnerable, such as individuals with impaired decision-making capacity. We advise and encourage course instructors to work with their students to minimize the potential of inadvertent disclosure of identifiable information obtained from people.

The IRB specifically encourages all instructors of courses employing these techniques to do the following:

- Require training in research ethics as part of the course structure.
- Require that students take and pass the [CITI on-line training](#) on human subject protection before collecting information from others.
- Review students' plans for projects. This may be accomplished, in part, by having students complete the IRB Initial Protocol Submission Form with follow-up instructor review and feedback on needed improvements on design and protections for confidentiality.
- Explain ways in which students should be attentive to the welfare of individuals and work to minimize risk particularly in cases involving:
  - Vulnerable populations, such as young children, prisoners, or individuals with impaired decision-making capacity,
  - Any reasonable possibility of physical, psychological, social, or economic harm to students or other individuals, or
  - Topics related to sexual activity, victimization or abuse, use of alcohol or illegal drugs, or involvement in illegal activity
- Require printed instructions/information that explain the use of the data for coursework and include the name and contact number of the instructor.
- Require, whenever possible, anonymous data collection so that the data are not linked to individuals.
- Instruct students in the strategies recommended by the IRB to deal with potential privacy and confidentiality issues when collecting demographic data - see

[https://webcapp.ccsu.edu/appFiles/list/262/CCSU\\_IRB\\_Guidelines\\_for\\_Collection\\_of\\_Demographic\\_Data\\_in\\_Research\\_Studies.pdf](https://webcapp.ccsu.edu/appFiles/list/262/CCSU_IRB_Guidelines_for_Collection_of_Demographic_Data_in_Research_Studies.pdf)

- Require destruction of individuals' data at the end of the course or within a short time afterward.
- Instruct students about the privacy and security vulnerabilities associated with computers.

#### Reference and Thank You.

The foundation and many specifics of this draft proposal come from the web resources of the Human Research Protection Program at the University of Michigan. We thank them for their generous permission to use and adapt their web resources on this topic (Permission granted on 11.20.18 by Lois Brako, Ph.D., Assistant Vice President for Research - Regulatory and Compliance Oversight, University of Michigan). See: <https://research-compliance.umich.edu/human-subjects/human-research-protection->