

Classroom Research Activities: Undergraduate Human Subjects Research Guidelines

CWRU Writing Program & SAGES: Fall 2017

The Writing Program and SAGES value research and writing, and encourage instructors to engage students in classroom activities that involve these skills. Such activities foster intellectual curiosity, promote engagement with people and ideas, and provide opportunities to learn about ethical research practices. To that end, instructors and students who engage in research should do so in compliance with federal regulations and in keeping with CWRU's institutional mission as it applies to undergraduate research.

The following provides guidance from the CWRU Institutional Review Board (IRB). The Writing Program and SAGES endorse this guidance and recommend that instructors who plan and facilitate research activities, particularly those that involve research techniques involving interaction with living people or private information (e.g., interviews and surveys), familiarize themselves with the definition of human subjects research (HSR).

Classroom research activities that meet the HSR definition are subject to IRB regulations. Such projects must receive prior IRB approval if there is an intent to present or publish any essays, oral presentations, or other products from that research, for example at the Celebration of Student Writing and Research, as a SAGES Essay Prize winner, or as an article.

Guidance from the Office of Research Administration: Student Activities that May Constitute Human Subjects Research (HSR)

All human subjects research (HSR) conducted by CWRU students is governed by a federal regulation known as "The Common Rule." This regulation defines human subjects research as activities that are 1) "designed to develop or contribute to generalizable knowledge" and 2) involve a living individual about whom the researcher obtains either data through intervention or interaction, or identifiable private information (45 CFR 46.102d and f).

To determine whether an activity is subject to the regulations governing human subjects research, it is necessary to consider both the nature of the interaction with individuals or their private information, and whether the activity is designed to develop or contribute to generalizable knowledge.

When an activity is designed to develop or contribute to generalizable knowledge, there is intent to share results in a public way (such as a journal article, scientific poster, conference presentation, or other forum) so as to add to a body of scholarly or academic work. Whether or not publication eventually occurs, scholarly intent at the time of interaction or data collection determines applicability of the rule.

Examples:

A history project investigating archived diaries from the Civil War era does not involve living persons or identifiable private information about living persons. Therefore, regardless of whether there is intent to develop or contribute to generalizable knowledge, it is not human subjects research.

A student who queries classmates about their flavor preferences for an ice cream party is interacting with living individuals to obtain data, but is not conducting a systematic investigation that produces generalizable knowledge.

But, a student who plans to survey individuals about their exercise habits and present the findings at a public poster talk or publish them in an article or on a website is conducting human subjects research and therefore is subject to oversight by an Institutional Review Board (IRB).

Instructors who assign projects that meet the federal definition of human subjects research should take the following steps:

1. Consult the CWRU IRB *before* assigning the project to students in order to confirm that the project in fact does constitute human subjects research. In most cases, the IRB can make a determination over the phone. Call IRB Manager Sue Ambro at 368-4514 or 368-6925.
2. If the project requires IRB review or exempt registration, initiate that process. Depending on the circumstances, the CWRU IRB may be able to issue a blanket protocol to the instructor that will cover all students in a course.
3. Educate students about the ethical use of human subjects in research. Please visit the CWRU IRB webpage for helpful resources: <http://case.edu/research/faculty-staff/compliance/irb/>.

Not every academic project or activity involving human participants meets the federal definition of human subjects research.

Class projects that involve human participants and the teaching or practicing of research methods/techniques, but are not designed to develop or contribute to generalizable knowledge do not meet the federal definition of HSR.

Thus, instructors can assign projects or activities through which students may practice valuable research skills, but which do not require IRB oversight, as long as those projects or activities are not assigned with the intent to share results in a public way to add to a body of scholarly or academic work. Instructors who assign such non-HSR projects or activities should take the following steps.

1. Consult with the CWRU IRB to confirm that the project or activity in fact does not constitute human subjects research. In most cases, the IRB can make a determination over the phone. Call IRB Manager Sue Ambro at 368-4514 or 368-6925. If desired by the instructor or required by another entity, the IRB office can provide a letter stating that the project or activity does not meet the definition of HSR.
2. Clearly communicate to students that any such project or activity cannot be presented or published as HSR because it is not designed to develop or contribute to generalizable knowledge.
3. If the project or activity is not HSR but involves human participants and may entail presentation or publication (e.g., a poster at Research ShowCASE or publication on a course webpage), it should be labeled as not meeting the federal definition of HSR. For such cases, it is strongly recommended that a letter stating that the project or activity does not meet the definition of HSR be obtained from the IRB prior to initiating the project.

Note: Projects that are not HSR and therefore do not require IRB review and oversight may still present risks to human participants and thus call for the exercise of ethical practices. In such instances, instructors are encouraged to consult with the IRB about how to handle matters such as informed consent, privacy, and professional ethics.

If you have any questions about HSR or classroom activities that potentially involve HSR, please contact the CWRU IRB office at 368-4514 or 368-6925. For helpful resources, visit <http://case.edu/research/faculty-staff/compliance/irb/>.