Cleveland State University

Office of Sponsored Programs and Research
Institutional Review Board (IRB)

Student Research Projects and Approval by CSU's Institutional Review Board

It is the policy of Cleveland State University that research projects involving human participants must receive approval from the Institutional Review Board (IRB) before the research is conducted. The University has stated this policy to the Office of Protection from Research Risk (OPRR) of the Public Health Service (PHS), and in its assurance agreement with OPRR has pledged to be in compliance with the relevant federal regulations (45 CFR 46), a pledge that includes both faculty and student research. To reaffirm and implement this pledge, the University Graduate Council considered the following statement in its November 10, 1998 meeting, and adopted it as part of the University's official policy regarding research:

> *The University requires that all students apply for and receive approval from the Institutional Review Board prior to conducting research with human participants when that research constitutes a requirement for the student's degree. The University as fulfilling any requirements for the degree will accept no research project that required but failed to receive prior IRB approval.*

Please note that this statement does not alter University policy regarding student or faculty research. It merely makes it explicit that the policy applies to student projects such as theses (B.A. and M.A.) and dissertations (Ph.D.)

All research results using human subjects presented at conferences/workshops/seminars by Cleveland State University faculty/staff/students must have prior IRB approval.

Any Cleveland State University faculty, staff, or student who recruits any member of the CSU community for use in human subject research must obtain Institutional Review Board approval before the research is conducted.

Implementation

The policy is effective August 30, 1999. By this, Graduate Council and the IRB mean that any student research project that begins on or after this date must obtain prior IRB approval. Please note that ongoing projects that have not been approved may be submitted to the IRB so that future data collection is in compliance with the regulation and policy. The IRB does not grant retroactive approval, however.

To inform the University community, a copy of this explanation sheet is being sent to all Deans and Department Chairs, all Graduate Program Directors, all Directors of Undergraduate Honors Programs, and all members of the Graduate Faculty. In addition, all current students who either enrolled in research-related courses or are enrolling in such courses, are being sent the explanation sheet. It is the responsibility of Graduate Program Directors and faculty advisers to make sure that future students are aware of the policy.

The sheet contains important information concerning research projects that do and do not require IRB approval, to assist you in determining which student projects will be affected by the policy. Please note that this information applies equally to faculty as well as student research, *and that all research involving human subjects must be evaluated by the IRB to determine if it requires approval by the Board.* To obtain an application for project approval, download the application form from the web at the following address:

http://www.csuohio.edu/offices\spr\irb\irbprotocolsubmissionforms\index.html

Mailing Address: 2121 Euclid Avenue, PH-3rd Floor • Cleveland, Ohio 44115-2214
Campus Location: Parker Hannifin Hall • 2258 Euclid Avenue • Cleveland, Ohio
(216) 687-3630 • Fax (216) 687-9382

Terminology

Research. The relevant federal regulation (45 CFR 46) defines the term "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (p. 6, section 46.102.d). These activities include experiments, survey and questionnaire procedures, and any other activities in which a human subject's behavior is observed, recorded, or manipulated. Activities (and examples) that fit the definition of research include:

a. An experiment on the accuracy of human long-term memory.
b. Applying a traditional clinical method to a new problem; for example, seeing if traditional physical therapy methods work for a new type of patient.
c. Telephone surveys of randomly selected participants, to determine their views on political, civic, or cultural issues.

Activities (and examples) that are not considered research under this policy include:

a. Classroom demonstrations; for example, asking students to remember lists of words, to demonstrate principles of short- or long-term memory.
b. Clinical applications; for example, speech or physical therapy activities with a stroke victim.
c. Institutional surveys; for example, collecting demographic and enrollment data on a sample of the CSU student body.

Human subjects. In the regulations, "Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information" (p. 6, 46.102.f.). Accordingly, even recording information anonymously (e.g., children's test scores from school files) involves research on human subjects, because in principle the investigator had access to the individual's identity. Conversely, research that does not conform to this definition, or which does not record private information does not fall under the supervision of the IRB. Such projects would include:

a. Obtaining data from a public database such as the U.S. Census or the National Archive of Computerized Data on Aging. Why? Because the investigator could not in principle know who the individual participants had been when the data were obtained.
b. Measuring or assessing human bone samples taken from either anonymous tissue banks or settings such as archaeological sites (non-living).
c. Recording the number of pedestrians who cross a downtown intersection against the light at different times of day (not private information, no intervention or interaction).

Risk. The purpose of the federal regulation is to protect human subjects from research risks. Assessing whether a project puts subjects at risk, or whether the potential benefit outweighs the risk, is the sole responsibility of the IRB. Investigators may not "exempt" their own projects from IRB review simply because they judge the research to involve little or no risk.