

**CARDINAL STRITCH UNIVERSITY
INSTITUTIONAL REVIEW BOARD**

DEFINITIONS OF RESEARCH

INCLUDING THE DISTINCTION BETWEEN TEACHING ACTIVITIES AND RESEARCH PROJECTS

A. INTRODUCTION

The purpose of the Institutional Review Board (IRB) is to protect the rights of individuals participating in research (e.g., ensuring that participation is voluntary) and to protect participants from research risks (physical and psychological). This is both an ethical and legal obligation. Federal guidelines require that human research be reviewed by an IRB.

Most, but not all, activities in which data are gathered from people are considered research. Research is defined by the Federal *Office for Human Research Protections* (OHRP) as:

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of the *Health and Human Services* (HHS) regulations, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

OHRP gives each IRB the option of determining additional activities involving human participants that must be reviewed by the IRB.

The distinction between research and normal classroom activities is not always clear. Therefore, it is **ESSENTIAL THAT ALL CLASSROOM INSTRUCTORS READ THE FOLLOWING INFORMATION.**

B. ACTIVITIES INVOLVING HUMAN PARTICIPANTS WHICH MUST BE REVIEWED BY THE IRB ¹

1. RESEARCH

- Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, not primarily for the benefit of the research participants. This includes, but is not limited to
 - Publicly available results: All studies that will be published or presented at a scientific conference or other public forums. Publicly available results include reports given to the person or agency being studied (as may occur in certain capstone courses). Many scientific and educational organizations require IRB approval for publication.
 - Risk: Studies that may cause physical or psychological harm.
 - Protected populations. Studies that involve minors (17 years of age or younger), pregnant women and fetuses, prisoners, individuals with disabilities (mental, learning, emotional, or cognitive), or people not capable of making an informed decision concerning participation.

- Sensitive issues: Studies concerning issues that could negatively affect the participant's employment, financial standing, reputation or social status if the participant's identity was revealed. This includes illegal conduct, drug use, sexual behavior, or behaviors that could expose the participant to civil liability. It is the responsibility of the IRB, and not the principal investigator, to determine if it is likely that the participants' identities could be revealed.
- Deception: Studies in which participants are either given information that is not true or are not given enough information to make an informed decision whether or not to participate in the study.
- Federal funding: All studies that receive federal funding must have IRB approval.
- Examples
 - A faculty member performs a study correlating class absences to course grades in traditional and non-traditional students. The study will be submitted for presentation at a conference. Even though students' names will not appear in the presentation, the study is generating new knowledge and will be publicly available, and thus must be reviewed by the IRB.
 - An administrator distributes a written survey to staff asking questions about drug use. Though the survey does not ask that the respondent's name be provided, demographic questions such as age, gender and department are asked (which could potentially identify the respondent). Due to the sensitive nature of the topic and the potential for the respondents to be identified, IRB review is required.

2. CLASSROOM ACTIVITIES

- The following guidelines apply to activities conducted in classroom situations; that is, where a member of the University teaching staff is employed in a contractual relationship to deliver instruction to students who pay tuition or are legally required to be in school.
- Certain class projects, studies, or activities are considered research or have the potential to violate the rights of students. The following activities must be reviewed by the IRB:
 - Systematic collection of human data by faculty or students, within or outside the classroom (e.g., surveys, interviews or observation of public behavior), that will be analyzed with the intent of generating new knowledge not primarily for the benefit of the participant (i.e., the data increase academic or scientific understanding on the topic being studied).
 - Systematic collection of human data by faculty or students in which the results and conclusions will be publicly available outside of the classroom (e.g., a report, poster, conference presentation, publication).
 - Any activity that involves physical or psychological risk, protected populations, sensitive issues or significant deception. This applies even if the students in the class serve as participants, the results will not contribute to generalizable knowledge, or results will not be made public.
 - See below for exceptions to these requirements.
- Examples
 - As part of a course requirement, students will conduct an experiment determining people's opinions of their own bodies either after reading a fashion magazine or a news magazine. The intent is to analyze the data and present the study at a university poster session. Even though participants' identities will remain anonymous, new knowledge is being generated and will be made public, and thus the project must be reviewed by the IRB.
 - An instructor intends to demonstrate the effect of humor on pain tolerance. Students in the class will watch either humorous or neutral video clips while immersing their hands in ice water. The goal is to keep the hand immersed as long as possible. Since this study could potentially cause physical harm, it must be reviewed by the IRB.

- Students are required to interview 7th grade students about their opinions on physical education classes. The intent is to give college students experience with interviewing children. Results will be discussed in class, but data will not be analyzed or presented outside the classroom. Regardless, the fact that a protected population will be studied requires IRB review.

C. ACTIVITIES WHICH ARE NOT CONSIDERED RESEARCH AND ARE EXEMPT FROM IRB REVIEW (i.e., a research protocol does not need to be submitted to the IRB) ¹

1. Course activities:

- Classroom demonstrations, surveys, observations or interviews (whether the students enrolled in that class serve as participants or data are collected outside the classroom), do not need to be submitted to the IRB if ALL of the following circumstances apply:
 - The intent is to give the students experience with research methodology and data collection OR data are collected for the direct benefit of the participant.
 - Data will not be analyzed with the intent of generating new knowledge or increasing academic or scientific understanding on the topic being studied. That is, the study is expected to produce only findings that have already been established.
 - Data will not be made public outside of the classroom (e.g., published, displayed or presented at a conference).
 - Students/participants will not be subjected to physical or psychological risk, they do not belong to a protected population, and they will not be asked to divulge sensitive information.
- Examples
 - An instructor requires students in a class to develop and administer surveys to other students in that class about their opinions on academic misconduct. The IRB would not review this project since the purpose is to give the students experience with survey construction and data collection and their opinions would not affect their academic reputation. However, if the surveys asked students about their *personal* experiences with academic misconduct, their responses could potentially harm their reputations. Even if the surveys were to be returned anonymously, it is possible their identities could be determined based on their handwriting, responses to certain demographic questions, etc. In this case, the activity must be reviewed by the IRB.
 - An instructor requires each student in a course to interview the manager of a mid-sized corporation. No sensitive questions will be asked. This information will subsequently be discussed in the classroom. The activity does not contribute to generalizable knowledge and no results of this survey or interview will be formally presented outside of the classroom. This activity would not be reviewed by the IRB. IRB approval would also be unnecessary if a final report was sent to the individual participant and that report only referred to the data provided by that participant. If, however, the results of the interviews were formally written up and sent to the corporations (i.e., someone other than the participant), the project would be reviewed by the IRB.

2. Research conducted in established or commonly accepted educational settings, involving normal educational practices. For example

- Research on regular and special education instructional strategies.
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews or observation of public behavior **UNLESS**
 - Participants can be identified (directly or through identifiers linked to the participants)

AND

 - Disclosure of their responses could place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.
 - The above restrictions do not apply to elected or appointed public officials or candidates for public office unless federal statutes require confidentiality (and thus IRB review).
4. Collection of existing (or archival) data, documents, records, pathological specimens, or diagnostic specimens, that are publicly available.
 - The term "existing data" applies to retrospective studies involving already collected data where data must be "on the shelf" when the protocol is initiated. For research supported on NIH grants or contracts, the data should be in place when the application or proposal is submitted for IRB review.
 - "Publicly available sources" refers to sources such as telephone books and public records. Although there are organizations that make data sets broadly accessible at reasonable cost to the research community, these materials are not usually available to the public at large. If you obtain data from any of these sources, you should not assume that the source meets the definition of "publicly available."
 - If existing data are not available to the general public, a protocol must be submitted to the IRB even if the data are considered by the principal investigator to be recorded in a way such that the individuals cannot be identified (directly or through identifiers linked to the participants). That decision must be made by the IRB.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs;
 - Procedures for obtaining benefits or services under those programs;
 - Possible changes in or alternatives to those programs or procedures; or
 - Possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies
 - If wholesome foods without additives are consumed or
 - If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

¹Items in this list were taken from the following sources:

- The Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects (HHS, OHRP); [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101\(b\)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101(b)).
- Correspondence with OHRP's Division of Education and Development.

For further details and other exemptions, see Title 45 Part 46.101
[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101\(b\)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101(b)).

D. COURSE ACTIVITIES and ETHICAL CLASSROOM PRACTICES

1. Are all course activities considered research? OHRP states that “Often student projects do not meet the regulatory definition of research. A student project must be both a systematic investigation and must be designed to develop or contribute to generalizable knowledge in order to be considered research under the HHS regulations at 45 CFR 46. For example, a student project that is designed to demonstrate for educational purposes how research methods and procedures can be used, and is expected to produce only findings that have already been established, would not be considered research under the HHS regulations. Student projects that do not meet the criteria of being a "systematic investigation, designed to develop or contribute to generalizable knowledge", do not need IRB review and approval and can be supervised by the educator(s) responsible for guiding student educational exercises without IRB oversight.” However, to make that determination, instructors considering such projects must complete the IRB training ([On-Line IRB Training](#)).

2. IRB protocols in capstone and accelerated courses. Certain capstone and accelerated courses meet for such short periods of time as to make it difficult to write, submit, and have a protocol approved in time to collect data. In cases where an IRB protocol is required, but the time is limited, a “blanket protocol” can be written and submitted by an instructor in advance of the course. For example, if students in an 8-week course are required to conduct interviews, the instructor (who has completed IRB training) may submit a blanket protocol that sets the parameters for all combined studies. This would be done in lieu of having each individual student submit a protocol. However, these students are still required to complete IRB training. Also, any individual student project involving risk, protected populations, sensitive issues or deception must be reviewed by the IRB.

3. Ethical considerations. Although the IRB does not review all classroom activities, it is critical that data collected by faculty or students, regardless of its intent, be collected in a manner that treats all participants ethically. That is, regardless of whether or not class activities or projects meet the federal guidelines as research, both students within the class and people not associated with the class (from whom information will be collected) have the following rights:

- People must be aware that their participation is voluntary and that they can stop participation at any time.
- Physical or psychological risk must not be greater than that encountered in every day life.
- Information should not be collected from people that could negatively affect their employment, financial standing, reputation or social status if the participant’s identity was revealed, unless it can be guaranteed that their identities remain anonymous.

E. WHEN IN DOUBT.....

If you are in doubt about whether or not your research or activities need to be reviewed by the IRB

- Contact one of the IRB’s College Research Advisory Committee chairs
 - College of Arts and Sciences Advisory Committee
Terrance Steele (Box 518, 414-410-4474, tsteele@stritch.edu)
 - College of Business and Management Advisory Committee
Elizabeth Regimbal (952-835-6418 ex. 40, eeregimbal@stritch.edu)
 - College of Education and Leadership Advisory Committee
Joan L. Whitman (Box 375, 414-410-4343, jlwhitman@stritch.edu)
 - College of Nursing Advisory Committee
Sharon Garrett (Box 442, 414-410-4696, slgarrett@stritch.edu)

- Refer directly to the government policies
 - [OHRP guidance on Engagement of Institutions in Research](#)
 - [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101\(b\)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101(b))

F. FINAL NOTE

Please note that although an activity or study may require IRB review, this does not mean it will probably not be approved. Many studies involving potential risk, protected populations, and sensitive issues are approved as long as the rights of the participants are guaranteed. In cases where rights might not be protected, the IRB often makes suggestions that easily resolve potential problems.