

## *IRB Guidelines for*

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## Student/Classroom Research Projects

When the goal of the student project is to contribute to generalizable knowledge, Creighton University requires that all research involving human subjects conducted by faculty, staff, or students affiliated with the university be reviewed and approved by the Institutional Review Board (IRB) prior to initiation, regardless of the source of funding and regardless of its federal status as an exempt, expedited, or full review project. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB. The IRB further requires that all student research activities be supervised by a faculty member. However, some types of student research activities may not require IRB review above and beyond faculty supervision, because their goal is educational and not the dissemination of generalizable knowledge. Creighton University supports a wide range of both undergraduate and graduate student research projects using human subjects; from course-related research exercises to dissertation studies. This document is intended to clarify IRB policy and procedures as they relate to student and classroom research projects.

### **Independent Research Projects**

Independent research projects are those that employ systematic data collection with the intent of contributing to generalizable knowledge. Theses, dissertations, and honors research projects involving human subjects that are considered research as defined by 45 CFR 46 (i.e., “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”) *always* require review by the IRB. Investigations designed to develop or contribute to generalizable knowledge are those that seek to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. While such research is often disseminated through scholarly publication or presentation of the data, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to “generalizable (scholarly) knowledge” makes an experiment or data collection research, regardless of publication. For additional information regarding the submission and review of such projects, please visit the IRB [Investigator and Research Staff website](#) or contact the IRB Staff at (402) 280-2126 or [irb@creighton.edu](mailto:irb@creighton.edu).

### **Research Methods Training/Curriculum**

Research projects for which the overriding and primary purpose is a learning experience in the methods and procedures of research do not meet the federal definition of research and are therefore generally not subject to (i.e., are excluded from) IRB review/approval. Curriculum projects in which students conduct research involving human subjects need *not* be reviewed by the IRB if the following conditions are satisfied:

1. The project involves minimal risk to subjects (i.e., when “the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”). Student research projects that fit the categories below are generally considered minimal risk:
  - a) Research involving the use of educational tests, survey procedures, and interview procedures
  - b) Observation of public behavior if confidentiality or anonymity is maintained
  - c) Research with subjects who are elected or appointed public officials or candidates for public office, regardless of whether the subjects may be identified or the information is sensitive
  - d) Research on individual/group characteristics or behavior in such areas as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior, etc., provided that confidentiality or anonymity is maintained
  - e) Research employing oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
  - f) Collection of data from voice, video, digital, or image recordings for research purposes
  - g) Research involving the collection or study of existing data, documents, or records if one of the following is true: the sources are publicly available or the information is recorded by the investigator in a way that subjects cannot be directly or indirectly identified
2. The project does not involve sensitive topics or confidential information that could place a participant at risk if disclosed. Any interview, survey, or questionnaire that proposes to investigate opinions, behaviors, and/or experiences regarding, but not limited to, any of the following sensitive topics requires IRB approval:
  - a) Sexual orientation, incest, rape, sexual molestation, deviant sexual behaviors or attitudes regarding sexual conduct (pedophilia, bestiality, etc.), practices of contraception, abortion, and/or pregnancy
  - b) Substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics, and any prescription medication legally or illegally obtained
  - c) Questions regarding mental health (e.g., suicide depression, obsessive-compulsive behaviors including, but not limited to, drug use, underage drinking, gambling, eating disorders, etc.)
  - d) Traumatic experiences of an individual (e.g., being a victim of violence including child abuse, senior abuse, war or combat experiences of veterans)
3. The project does not involve persons from certain vulnerable populations as participants. For the purposes of classroom research, vulnerable populations who may not be included are: pregnant women, fetuses, children (with the exception of observational studies and college freshmen who are younger than 19 years of age), prisoners, persons at high risk of incarceration or deportation, or mentally disabled. Projects involving such subjects **require** IRB review and submission of a protocol for approval prior to beginning the research.

The project must involve the voluntary participation of individuals without any coercion or pressure being placed upon them by the researcher. Though not required, it is recommended that

instructors/students consider providing a consent document to participants and fully informing them of the research in which they will be taking part.

The results of the project will never be distributed to professional conferences, journals or books, etc. However, the student may present findings on or off campus if the purpose is to educate the student in the academic process and not to disseminate generalizable knowledge. If the possibility exists that either the instructor or the student would consider disseminating the data as generalizable knowledge, the research must be submitted for IRB review. If after collection of data the instructor or student deems the results to represent generalizable knowledge worthy of dissemination, the instructor should immediately submit a protocol describing the method and results to the IRB for review/approval. Please note that approval under such circumstances is not guaranteed and any data collected under a classroom projects exclusion may not be disseminated prior to IRB approval.

### **Responsibility for Oversight of Student Projects/Classroom Activities**

Each faculty/department has the responsibility for:

1. Assessing whether student projects/classroom activities involving human participants meet eligibility for review or exclusion from IRB review,
2. Overseeing these activities, and
3. Ensuring that ethical principles are adhered to in the conduct of those activities.

Faculty advisors for both undergraduate and graduate students must be certified to conduct research with human subjects. [IRB Training Certification](#) is offered through the Creighton University Institutional Review Board. For questions regarding Creighton University's policies relating to the conduct of human subjects research, please visit the [IRB Policies and Procedures web page](#) or contact IRB Staff at (402) 280-2126 or [irb@creighton.edu](mailto:irb@creighton.edu).

With regard to classroom projects, faculty instructors are encouraged to become fully familiar with each student's project(s). It is also important that instructors who teach research methods courses educate students regarding the existence of IRB review and discuss the relevant ethical issues surrounding the use of human subjects in research. The instructors are encouraged to use the online ethics courses offered by the University. The Research Education Coordinator will assist faculty by tracking completion of specified online courses. The Research Education Coordinator can be reached at (402) 280-2680 or at [researchcomped@creighton.edu](mailto:researchcomped@creighton.edu). IRB staff are available to conduct presentations on human subject research in your class. For further information, please contact the IRB at (402) 280-2126 or [irb@creighton.edu](mailto:irb@creighton.edu).