ASU IRB Guidance Document

Classroom Research

Arizona State University (ASU) requires that all research involving human subjects conducted by faculty, students, or staff affiliated with the university, be reviewed and approved by the IRB prior to initiation, regardless of the source of funding, and regardless of its federal status as an exempt, an expedited, or a full review project. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB.

The IRB requires that all student research activities are supervised by a faculty member, but some types of student research activities may not require IRB review above and beyond faculty supervision.

ASU supports a wide range of both undergraduate and graduate student research projects using human subjects—from course-related research exercises to Ph.D. dissertation studies. Generally, student research involving human subjects falls into one of two categories, only one of which requires IRB Review:

- Independent research
- Research methods training not typically needing IRB review

**Independent Research**—Projects which employ systematic data collection with the intent to contribute to generalizable knowledge. **Thesis** and **dissertation** projects involving human subjects are considered research as defined by **45 CFR 46** and always require review the IRB.

The IRB considers results to be generalizable if they are expected to be submitted for publication in a journal or magazine, published in bound volumes such as theses or dissertations, presented at a professional conference or otherwise widely distributed.

**Methods Training/Curriculum**—Research projects for which the overriding and primary purpose is a learning experience in the methods and procedures of research to acquire knowledge and skill is typically not subject to IRB review. An example of this is research that is carried out by students as part of an applied project for research methods training. The type of research is further characterized by **minimal risk** (or null risk) to human subjects and clearly falls within ethical guidelines for the protection of human subject
participants in research. Important factors to consider are the potential risks to subjects posed by the research activity itself, in terms of:

1. Potential harm from subject participation in the study;
2. Possibility of disclosure of confidential information;
3. Whether the individuals are either unable to give consent or are subject to significant coercion or pressure to participate.

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(s) involve minimal risk to subjects; and
2. They are not studying Native Americans specifically
3. Results will never be distributed outside the classroom and/or institutional setting (including poster or showcase session or oral presentation to instructors and peers) or used for publication. If there is even a remote chance that the data or the report/manuscript will be used in the future for an off-campus conference presentation, or submitted for publication, the research should go through IRB review. If the project is not subjected to IRB review before data collection begins the information will most likely not be permissible for inclusion in future presentations, publications, or research.

To illustrate, consider a student who undertakes an individual or class project that does not involve a vulnerable population and involves no risk to the subjects of the study. The student delivers a presentation on campus (e.g., poster or showcase session or an oral presentation before faculty and peers.) This project would not require IRB review. However, if the results of this otherwise "no- or low-risk" project may/might be disseminated at a professional conference, submitted for publication, or published on the World Wide Web, government regulations require prior review by IRB.

If the results of the student project will be published or otherwise distributed off campus, in any form of media, the project must be reviewed by the IRB.

Although the IRB does not require review of classroom and curriculum projects, instructors are required to become fully familiar with each student's project(s), and to discuss it with the student. Experience has taught us that time spent with students discussing matters such as courtesy, and avoidance of unnecessary discomfort or invasion of privacy, will be time well spent. We believe that explicit recognition of the existence of Human Subjects Panels at all research institutions, and discussion of their goals and concerns, should be an integral part of introducing students to research methodologies. Similarly, faculty would do well to discourage inexperienced researchers’ enthusiasm to
conduct practice research projects with vulnerable populations.

If in doubt, it is wise to have the project reviewed or to ask for specific advice before the project begins. The IRB is unable to give post facto approval.

Training Requirements

Faculty advisors of both undergraduate and graduate students must be certified to conduct research with human subjects. One way of receiving certification is to complete the Computer-Based Training (CBT) program available through CITI. Information about the training requirement and link to the CITI website can be found on the office of Research and Integrity website at: https://researchintegrity.asu.edu/training/humans.

Responsibility for Oversight of Student Projects/Activities

The faculty and the department have the responsibility for (1) making the decision whether student research activities involving human participants meet eligibility for exclusion from IRB review; (2) overseeing these activities; and (3) assuring that ethical principles are adhered to in the conduct of those activities.

Specifically all participants must be invited to voluntarily participate and receive an explanation of what the activity is about and understand that their participation is voluntary, and the Principles of the Belmont Report regarding Respect for Persons, Beneficence and Justice should be adhered to when conducting the activity.

Definitions

Research is defined by federal guidelines as a systematic investigation designed to develop or contribute to generalizable knowledge and should be distinguished from potentially similar activities such as employing innovative teaching techniques and administrative data collection.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Minimal Risk (defined in 45 CFR 46, subpart A), exists 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 usually considered minimal risk:

1. Research conducted in an educational setting involving normal education practices, such as research that examines or compares regular and special education curriculum including but not limited to instructional strategies/techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests, survey procedures, and interview procedures.
3. Observation of public behavior if confidentiality or anonymity is maintained.
4. 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.
5. Research on individual/group characteristics or behavior or research employing oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies on areas such as perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, social behavior, etc. if confidentiality or anonymity is maintained.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if one of the following is true: the sources are publicly available or information is recorded by the investigator in a way that subjects cannot be directly or indirectly identified.