Appendix B



Guidance on Determining Whether IRB Review Is Required

**Do I Need IRB Review?**

The IRB reviews and approves all “research” involving “human subjects” that is carried out by WCIU students or personnel. The following definitions and guidelines are provided to help investigators determine if their work requires IRB review and approval.

For “international” research, i.e., research conducted outside of the United States, kindly refer to this link and comply with requirements (if applicable) of the research location: <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html> (an e-copy of this document is also available from the university’s IRB Board).

**Definitions**

**Research** — Federal regulations (CRF Title 45, Part 46, 2009) define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” This definition excludes instructional activities that are not designed to contribute in any way (e.g., through presentation or publication) to generalizable knowledge. Also excluded are activities related to routine course or program development/evaluation.

**Human Subject** — Federal regulations (CRF Title 45, Part 46, 2009) define a human subject as “a living individual about whom an investigator (whether a professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

In deciding whether an activity constitutes research involving human subjects, ask yourself the following questions:

**1) Will the data collected be publicly presented or published?**

**AND**

**2) Do my research methods involve a) direct and/or indirect interaction with participants via interviews, assessments, surveys, or observations, or b) access to identifiable private information about individuals, e.g., information that is not in the public domain?**

If the answer to both questions is “yes,” a project is considered research with human subjects and is subject to federal regulations. It thus requires a thorough review by the university’s IRB Board. The type of review required depends on the nature of the research project. Consult the sections on full, expedited, and exempt review (Appendix A Attachment 3) to make this determination.

The American Anthropological Association has established a Statement on Ethics guiding research that entails human experiences and this link will provide additional and useful details to guide this form of research: <https://www.americananthro.org/LearnAndTeach/Content.aspx?ItemNumber=22869>

**Activities That May Not Require Review**

The following activities do not typically require review because they do not satisfy the definition of “research”—in other words, the investigator answers “no” to the first question above. Most often the following activities are thought of as learning experiences only, since the information gathered will not be used as actual “data” for publication or presentation. However, information obtained via any of these activities would be considered research if it were incorporated into a publication or presentation that would be used to contribute to generalizable knowledge.

**Classroom Projects**

In many academic programs, a knowledge of research methods/methodology is vital to a well-rounded education. Instructors may encourage their students to design small projects simply to teach them how to properly conduct research. In most cases, the data will not be used to contribute to generalizable knowledge and may not require IRB review. However, they must be registered using the Faculty Assurance Form for Classroom Projects and submitted to the IRB. For more information, email the IRB: IRB@wciu.edu

**Program Evaluations**

Investigators may gather data from human subjects through direct or indirect interaction for purposes of program evaluation. The information they collect will not be used to contribute to generalizable knowledge, rather the results will be used to improve or develop an internal program.

Investigators are strongly cautioned to consider whether the information collected for a classroom project or program evaluation will be or will not be used to contribute to generalizable knowledge; **the investigator must decide in advance, as it is not possible to retrospectively review and approve a project once data collection has begun.** If an investigator is unsure about how the data will be used, it is better to err on the side of caution and apply for review.

Even when projects do not qualify as “research,” as defined by federal regulations, they must be conducted with the utmost regard for University policies, ethical standards, and the welfare of human participants.