Does the IRB need to review it?

Is this human subjects research as defined by DHHS regulations? Then Yes, the IRB must review it.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, 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. 28 C.F. R § 46.102(d).

What is a "systematic investigation"?

The term systematic investigation is generally thought of as a predetermined method for answering certain questions or studying a specific program or topic.

Examples include: program evaluations, program assessments, interviews, surveys, focus groups, and comparisons of groups.

What is "generalizable knowledge"?

An activity may be thought to develop or contribute to generalizable knowledge if the information collected can be applied beyond a particular program.

The following are examples of activities that would not contribute to generalizable knowledge:

If a program evaluation, program assessment, or other activity is used only for:

- internal improvements to a program or service.
- quality assurance purposes (e.g., customer satisfaction surveys).

The following are examples of activities that would contribute to generalizable knowledge:

If a program evaluation, program assessment, demonstration project or other activity is:

- conducted to examine whether the program had the desired effect on program participants, and that evaluation can inform other programs.
- conducted with the intent to replicate the program.
- designed to draw general conclusions.


designed to inform policymakers.

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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

So how do I conduct research that the IRB does not review?

See the Guidance on Non-Reviewable Research Activities are considered to be non-reviewable if they do not meet the definition of research or do not involve human subjects as defined under the federal regulations (45 CFR 46).

For questions regarding human subjects research contact Compliance Specialist, Jacqueline Reid at:

Office of Sponsored Programs
Sherman Hall, Room 320
Phone 309-298-1191 or
irb@wiu.edu
Guidance on Non-Reviewable Research

Activities are considered to be non-reviewable if they do not meet the definition of research or do not involve human subjects as defined under the federal regulations (45 CFR 46).

Example: Student Classroom Based Projects
IRB review of classroom-related activities is not required at WIU when the collection of information from people is exclusively for the purpose of writing a paper and earning a grade, since the activity would not meet the “generalizable knowledge” standard of research as defined in the Federal regulations. Also, IRB review of classroom-related activities is not required when the collection of information from participants is exclusively for the purpose of class discussion or for the purpose of training in research or research methods. Instructors who want written and official determination that their students’ classroom-related activity does not require IRB review may choose to submit the course syllabus with a Determination Form (located here: http://www.wiu.edu/sponsored_projects/compliance/index.php) to the Compliance Specialist via irb@wiu.edu for confirmation.

Even when IRB review is not required, activities designed to collect information from human participants should protect the rights of these participants. In such cases, the instructor remains responsible for educating students about the protection of human subjects and providing ethical guidance for all student projects. If the activity or data from the activity will be utilized outside the classroom in any way, it would require IRB review and approval. Both instructors and students are required to review and adhere to WIU’s Best Practices in Designing & Conducting Non-Reviewable, Classroom Based Research detailed below:

“Best Practices” in Non-Reviewable, Classroom-Based Research

The Institutional Review Board at WIU does not review research conducted by students solely to fulfill a course requirement, unless the student researcher or the faculty member intends to disseminate or generalize the data (e.g., by publishing, presenting/publishing an abstract or poster, or presenting the research at an academic conference which includes Undergraduate & Graduate Research Day conferences at WIU). Nevertheless, WIU has a strong interest in ensuring that all research at the university is conducted ethically. For this reason, WIU’s IRB has ratified the following “best practices” for faculty members who teach research methods courses and for students conducting research in order to fulfill course requirements. Human subjects research conducted to complete the Undergraduate Honor’s Thesis and Masters or Doctoral degree program requirements is not included in this policy, as these activities require IRB review and approval prospectively.

♦ Students engaging in non-reviewable classroom human subject research should complete the human subjects research ethics training module required for students by the WIU IRB. The link to the online CITI training course is available on the IRB webpage. In addition, students should carefully review important documents in the area of human subjects protection (i.e. Belmont Report; Declaration of Helsinki; World Health Organization Guidelines)
♦ Students are encouraged to develop data-gathering procedures that are consistent with the principles outlined in research ethics and human subject protection guidance and that incorporate methods to protect the confidentiality of the research data.
♦ Confidentiality and protection of research subjects should be the guiding principles in students’ research methods. Whenever possible, participants’ anonymity should be guaranteed.
Students are cautioned that anonymity and confidentiality have different meanings. Study data may not be appropriately described as “anonymous,” if the researcher collects participant names, other identifiable information, or audio- or video-recordings (see guidance on audio/video recordings). Additionally, study data might not be anonymous if a combination of data elements, such as birth date, occupation, and zip code, could reasonably be used to determine the identity of the participant. Study data may be “anonymous” when the researcher never records anything in the research record that identifies the participant. Study data may be anonymous even when the participant themselves are not completely anonymous to the researcher, for example in cases where interviews take place face-to-face, the participant is not anonymous, but the data can be recorded anonymously.

Conversely, for a study that involves the collection of names or identifiable recordings the researcher could indicate that all data will remain “confidential,” when research procedures ensure that participants’ data will not be shared outside the research team in an identifiable format and protections are in place to prevent an unexpected breach of confidentiality.

Students must become familiar with the principles of informed consent and be able to justify their consent processes to supervising faculty. A standard informed consent process includes:

- Using a consent document or script or information sheet that provides sufficient information for the participant to make an informed decision about whether or not they want to be in the research. See, e.g., “adult consent form” or assent templates at: [http://www.wiu.edu/sponsored_projects/compliance/index.php](http://www.wiu.edu/sponsored_projects/compliance/index.php);
- Ensuring that the consent document or script, or information sheet, is written at a language level appropriate for the population;
- Having an oral exchange with the participant about the substance of the consent form or information sheet;
- Asking the participant to recount key characteristics of the study (risk, benefits, activities), in order to confirm understanding;
- Collecting a signed & dated form from the participant, if appropriate; and
- Providing the participant or parent/guardian with a copy of the consent form or information sheet for future reference.

These steps apply, regardless of whether the student seeks consent from an adult participant, parental permission from a parent/guardian, or assent from a minor participant.

Should there be any possibility or intent to publish, present, or otherwise disseminate research data or findings outside the course, students must file an application for review called the Initial Review Form with the IRB prior to beginning recruitment or data collection. Students should name a faculty sponsor/advisor as Principal Investigator on that application and confer with that person and/or the Compliance Specialist about federal regulations, guidance, and local IRB policies governing human subject research at WIU.