

**Institutional Review Board (IRB)
Human Research Committee**

DETERMINING IF YOUR PROJECT IS CONSIDERED “RESEARCH” REQUIRING IRB REVIEW

Certain activities may have the characteristics of research but do not meet the federal definition of human subject research requiring IRB review. While consulting the Federal definitions of ‘research’ and ‘human subjects’ provided on pages 2-3, please complete the following table to help determine if your project meets these Federal definitions. A response of ‘yes’ to any of the questions may mean your project requires IRB review. If you respond ‘no’ to all of the questions, your project may not require IRB review. Submit this completed form to IRB@western.edu for review and with questions.

	YES	NO
1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the activity involve obtaining information about living individuals?	<input type="checkbox"/>	<input type="checkbox"/>
3. Does the activity involve interacting with humans or obtaining identifiable information about the subjects or identifiable biospecimens?	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the activity intended to generate new knowledge that will contribute to scientific literature (i.e. that revises or improves upon existing principles, theories, or knowledge?)	<input type="checkbox"/>	<input type="checkbox"/>
5. Are any of the project activities experimental (i.e. is there any testing of new or unproven treatments or strategies that are not yet known to be efficacious)?	<input type="checkbox"/>	<input type="checkbox"/>
6. Are the participants in the activity randomized to an intervention so that the results of the activity can be generalized to a larger population?	<input type="checkbox"/>	<input type="checkbox"/>
7. Does the activity involve additional risks imposed on participants in order to make the results generalizable beyond the participants themselves?	<input type="checkbox"/>	<input type="checkbox"/>
8. Is there an intent to publish or present the results of a human subjects research question to the scientific community?	<input type="checkbox"/>	<input type="checkbox"/>
9. Is there an evaluation/performance assessment part of the project in which information will be shared beyond those involved in or overseeing the program/process/system?	<input type="checkbox"/>	<input type="checkbox"/>
10. Will the results of a quality improvement program be disseminated outside the institution for the purpose of sharing the outcomes or implications of the project, not the process?	<input type="checkbox"/>	<input type="checkbox"/>
11. Will the activity be used to develop a problem statement, research questions, and/or theory-based hypotheses?	<input type="checkbox"/>	<input type="checkbox"/>
12. Is the study designed to prove a relationship or correlation?	<input type="checkbox"/>	<input type="checkbox"/>
13. The data will be used to create a presentation, poster presentation, and capstone paper or similar and that product will be preserved as an independent work.	<input type="checkbox"/>	<input type="checkbox"/>
14. You will be using the data in your honors project, dissertation or thesis.	<input type="checkbox"/>	<input type="checkbox"/>

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The answer is no if:

- You will be collecting the data only to improve your teaching skills, without sharing the data.
- If conduct EDUC action research, you will present the data only to the principal.
- You will be presenting the data only to your teacher, class members, and other Western Colorado University instructor, class members, and/or other students and faculty (not for honors project, capstone, thesis or dissertation). Project documentation, including a presentation, will be treated as a normal class assignment and not retained by the institution or instructor or reused by the student for any purpose.

Federal Definitions

Research is defined in the Code of Federal Regulations ([eCFR :: 45 CFR Part 46 -- Protection of Human Subjects](#)), as a **systematic investigation** designed to develop or contribute to **generalizable knowledge**.

- A **systematic investigation** involves a methodological procedure and plan, is theoretically grounded, and specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods.
- **Generalizable knowledge** is information that is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:
 - Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
 - Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

****Note that publication or other dissemination of findings does not in and of itself make the activity “research” unless the publication is expected to expand the knowledge base of a scientific discipline or other scholarly field of study such as in a database. It has been a long-standing myth that if you publish, IRB review is required. For ProQuest or other publications, consult with your instructor and the IRB chair about your particular project details.**

What isn't generalizable?

- A quality assurance/quality improvement/organizational effectiveness study where the intent is to assess, improve, or develop programs or services for an organization. Outcomes will remain specific to the organization, programs or services, although other organizations may use the results.
- An oral history or journalistic piece. These are published materials that are limited to only documenting or reporting on events, situations, policies, institutions, or systems without the intent to form hypotheses, draw conclusions, or generalize findings. It will not involve stories that will or may draw broad conclusions about the population, cultures, norms, and practices.

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Human subject is defined in the Code of Federal Regulations ([eCFR :: 45 CFR Part 46 -- Protection of Human Subjects](#)), as a living individual about whom an investigator (whether faculty or student):

Obtains information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

Obtains, uses, studies, analyzes, or generates **identifiable private information** or **identifiable biospecimens**.

- **Intervention** includes physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or their environment 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

To qualify as human subject research and require IRB review, the proposed research must fulfill BOTH definitions of research and human subject.