

POLICY

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Approved By: President Sabah Randhawa

Authority: [45 CFR 46](#); [The Belmont Report](#)

See Also:

Policy#

[PRO-4520.08](#)

[POL-U4520.02](#)

[POL-U5315.21](#)

[WWU Manual](#)

Policy Title

Protecting Human Subjects in Research

Addressing Responsible Conduct of Research

Protecting Children and Vulnerable Adults and Reporting Concerns of Safety or Welfare

WWU Human Subjects Research Compliance Manual

POL-U4520.08

PROTECTING HUMAN SUBJECTS IN RESEARCH

This policy applies to individuals in colleges, departments, and units conducting human subjects' research.

Definitions:

Human Subject:

A living individual about whom an investigator (whether professional or student) conducting research obtains, uses, analyzes, studies, or generates information or biospecimens through intervention or interaction with the individual; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Also referred to as a "Human Subject." 45 CFR § 46.102(e).

Identifiable Information:

Information by which the identity of the subjects may be ascertained by the investigator or associated with the information (i.e. the identity of the subject is or may be readily ascertained by the investigator or associated with the information). 45 CFR § 46.102(e)(5).

Informed Consent:

A process, whether written, electronic, or oral, in which the research provides prospective subjects with the information that a reasonable person would want to have in order to make an informed decision about whether to participate. The process of informed consent shall be documented by a written informed consent form, unless otherwise approved by the IRB. 45 CFR § 46.116(a) & 46.117

Vulnerable Populations:

A population in which some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, persons with impaired decision-making capacity, or economically or educationally disadvantaged persons. 45 CFR § 46.111(a)(3)

POLICY

Institutional Review Board (IRB):

A committee of at least five members including faculty, a community member not affiliated with the University, and the Research Compliance Officer. 45 CFR §107(a). The IRB reviews and approves research involving human subjects. The purpose of the IRB is to ensure that all human participant research be conducted in accordance with all federal, institutional, and ethical guidelines

Interaction:

Any communication or interpersonal contact between the investigator(s) and subject(s) whether online, in person, via survey, interview, or behavioral observation. 45 CFR § 46.102(e)(3)

Intervention:

Includes both the physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. 45 CFR § 46.102(e)(2)

Investigator:

Any person who is responsible for the design, conduct, or reporting of the human subjects research (includes faculty, staff, students, and collaborators). An investigator is anyone who has contact with the research subjects, collects, or analyzes identifiable data as well as the research advisor of any student conducting human subject research. 45 CFR § 46.102(e)(1)

Minimal Risk:

The probability and magnitude of harm or discomfort anticipated to be experienced are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR § 46.102(j)

Private Information:

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 which the individual can reasonably expect will not to be made public. 45 CFR § 46.102 (e)(4)

Identifiable Private Information:

Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. 45 CFR § 46.102(e)(5)

Review:

Evaluation of proposed research protocols by the IRB. The types of review include:

- **Exempt from Review** – Some human subject research is exempt from more substantive IRB review. However, the investigator is nevertheless required to submit an application to the IRB for its evaluation and receive an official exemption determination memo before any research may commence. Such research must constitute minimal risk to the subjects. 45 CFR §46.104(d)

POLICY

- **Expedited Review** – Some human participant research qualifies for expedited IRB review. Such research must constitute minimal risk to research subjects and data are collected through non-invasive techniques such as finger-stick blood samples, electroencephalogram (EEG) or moderate exercise. It can also include research involving identifiable data collected by a different researcher. 45 CFR § 46.110 & 63 FR 60364-60367
- **Full Review** – IRB review of human subject research that does not qualify as exempt from review or for expedited review.

Research:

A systematic investigation, including research development, testing, and evaluation that is designed to develop or contribute to generalizable knowledge. 45 CFR § 46.102(I).

Research Compliance Officer (RCO):

A University employee in the Office of Research and Sponsored Programs charged with administering Human Subjects Research protocols.

1. The Minimum Standards of Human Subject Research are Established by Code of Federal Regulations, Title 45, Part 6 (45 CFR § 46).

Research involving humans at Western Washington University is guided by the ethical principles regarding research involving human set forth subjects in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Belmont Report). The Belmont Report and 45 CFR § 46 establish the basis for the definitions below and the value of protecting the rights of human research subjects, while facilitating the highest quality research. Western Washington University's policies and guidance on this subject, including the [WWU Human Subjects Research Compliance Manual](#), are administered by the Office of Research and Sponsored Programs.

2. Research and Sponsored Programs (RSP) Oversees Human Subjects Research Compliance

3. Investigator(s) Conducting Human Subjects Research Must Obtain IRB Approval Prior to Collecting Data

4. Investigator(s) Must Complete Ethics Training Prior to Protocol Submission

Ethics training may be accomplished by passing the Collaborative Institutional Training Initiative (CITI) Social & Behavioral Basic/Refresher Course, or an acceptable substitute approved by the IRB.

5. Investigators Must Renew Ethics Training Every Five Years

6. Investigators Conducting Human Subjects Research Must Submit a Descriptive Research Protocol to the RCO

POLICY

The human subjects research application must include:

- a) A description of the hypothesis or research question, research methods, and procedures,
- b) An adequate data management plan,
- c) A description of the informed consent process and an informed consent form, or a request for waiver of informed consent, and
- d) The signatures of the lead investigator, the department chair (or the investigator's supervisor), and, if the researcher is a student, the signature of the faculty advisor.

7. Students Conducting "Human Subjects Research" Defined by Federal Regulations Must Obtain IRB Approval

Examples include, but are not limited to, an Independent Study Class, an Honors thesis, or a Graduate School thesis where the intent is to conduct a systematic investigation designed to contribute to generalizable knowledge.

Student activities in classrooms that do not meet and will never meet the definition of human subjects research, does not require IRB review, for example, activities that are solely to learn about the research process and not designed for or ever used for generalization.

8. IRB Determines the Level of Review of Human Subjects Research Applications

Investigator must submit all human subjects research protocols to the IRB. The IRB, not the investigator, determines whether the protocol warrants exempt, expedited, or full committee review.

9. IRB Reviews all Research Protocols Involving Human Subjects

The IRB must review all research protocols involving human subjects to confirm:

- a) Risks to subjects are minimized,
- b) Risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, and the importance of knowledge that may reasonably be expected,
- c) Selection of subjects is equitable, i.e., the criteria for selecting certain groups or individuals to participate in a study are methodologically related to the goals of the research,
- d) Subjects are adequately informed of their rights and the risks involved, and informed consent is documented,

POLICY

- e) Data obtained from the research are maintained in a manner that protects the confidentiality of the data and the privacy of the subjects, and
- f) Where subjects are likely to be vulnerable to coercion or undue influence, appropriate safeguards have been included in the study to protect the rights and welfare of the subjects.

10. Investigators Must Obtain Informed Consent from Research Subjects

Investigators must obtain written acknowledgment that the subjects understand their benefits, risks, and rights regarding the research unless the IRB grants a waiver or authorizes an alteration to the written informed consent requirement. 45 CFR 46.116(d)

11. Investigators Must Comply with WWU Record Retention Rules

Investigators must retain all IRB documentation, data, and signed informed consent forms or records from all research subjects for six years following the completion of the data collection.

12. Investigators Must Report Certain Issues

Investigators must report possible deviations from the approved protocol to a Research Compliance Officer. Possible deviations include:

- a) Unanticipated problems,
- b) Possible non-compliance, and
- c) Other information that might affect IRB approval of the protocol.

13. An Investigator's Failure to Comply with the Protecting Human Subjects in Research Policy May Constitute Research Misconduct Under University Policy [POL-U4520.02](#) Addressing Responsible Conduct of Research