

POLICY

Effective Date: March 8, 2016

Approved By: President Bruce Shepard

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

See also: [PRO-U4520.08A](#) Protecting Human Participants in Research
[POL-U4520.02](#) Addressing Responsible Conduct of Research
[POL-U5315.21](#) Protecting Children and Vulnerable Adults and Reporting
Concerns of Safety or Welfare
[WWU Human Participant Research Handbook](#)

POL-U4520.08

PROTECTING HUMAN PARTICIPANTS IN RESEARCH

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

Research involving humans at Western Washington University is guided by the ethical principles regarding research involving human participants set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Belmont Report). The minimum standards are established by Code of Federal Regulations, Title 45, Part 6 (45 CFR § 46). The Belmont Report and 45 CFR § 46 establish the basis for the definitions below and the value of protecting the rights of human research participants, while facilitating the highest quality research. Western Washington University's policies and guidance on this subject, including the [WWU Institutional Review Board Handbook](#), are administered by the Office of Research and Sponsored Programs.

Definitions:

Human Participant (Participant): A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. Also referred to as a "Human Subject." 45 CFR § 46.102(f)

Human Participants Research: Intervening or interacting with live human beings, manipulating the participants' environment, or obtaining identifiable or private information or identifiable human biological specimens from any source for research purposes. 45 CFR §102(f).

Human Participant Research Ethics Training Certificate (Ethics Training): A certificate issued by the National Institutes of Health (NIH) course entitled "Protecting Human Research Participants" or Collaborative Institutional Training Initiative (CITI).

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Alternative methods of meeting the training requirement must be approved by the Institutional Review Board (IRB). Alternative training must include discussion of research ethics, the voluntary nature of research participation, the consent process, and standards for maintaining the anonymity of participants and confidentiality of participants' data.

Identifiable Information: Information by which the identity of the participants may be ascertained by the investigator or associated with the information (i.e. the identity of the participant is or may be readily ascertained by the investigator or associated with the information). 45 CFR § 46.102(f)(2)

Informed Consent: A document written in language understandable to the participants that informs the research participants of their legal rights, the risks and benefits of participating in the research, the extent, if any, to which confidentiality of records identifying the participant will be maintained, and a statement that participation is voluntary. 45 CFR § 46.116(a)

Vulnerable Populations: A population in which some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. 45 CFR § 46.111(a)(3) & 111(b)

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 participants. 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 participant(s) whether online, in person, via survey, interview, or behavioral observation. 45 CFR § 46.102(f)(2)

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

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

Minimal Risk: The probability and magnitude of harm or discomfort anticipated to be experienced by the participant 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(h)(1)

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 which has been

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provided for specific purposes by an individual and which the individual can reasonably expect not to be made public. Private information must be individually identifiable in order to constitute human participant research. 45 CFR § 46.102(f)(2)

Review: Evaluation and approval of proposed research protocols by the IRB.

- **Exempt from Review** – Some human participant research is exempt from substantive IRB review. However, the investigator is nevertheless required to submit a protocol to the IRB for its evaluation and approval before any research may commence. Such research must constitute minimal risk to the participants. Exempt research includes research conducted in established or commonly accepted educational settings, surveys, interviews, observation of public behavior, and study of existing de-identified documents or data. 45 CFR § 46.101(b)
- **Expedited Review** – Some human participant research qualifies for expedited IRB review. Such research must constitute minimal risk to research participants and data are collected through non-invasive techniques such as electroencephalogram (EEG), moderate exercise, and audio or video recording participants. 45 CFR § 46.110(b) & 63 FR 60364-60367
- **Full Review** – IRB review of human participant research that does not qualify as exempt from review or for expedited review.

Research: A systematic investigation that is designed to develop or contribute to generalizable knowledge (45 CFR § 46.102(d)). It includes, but is not limited to, any research that is presented at a conference or for submission for publication as well as pilot projects.

Research Compliance Officer (RCO): A University employee in the Office of Research and Sponsored Programs charged with administrating Human Participant Research protocols.

1. **Research and Sponsored Programs (RSP) Oversees Human Participants Research Compliance**
2. **Investigator(s) Conducting Human Participant Research Must Obtain IRB Approval Prior to Collecting Data**

Exception: Research for quality assessment or quality improvement does not require IRB review, for example, a survey of demographics for internal use at the University or a survey of satisfaction or effectiveness of a University program so long as it will not be published or presented at a conference.

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

Ethics training may be accomplished by passing the National Institute of Health (NIH) course entitled “Protecting Human Research Participants”, the Collaborative Institutional Training Initiative (CITI), or an acceptable substitute approved by the IRB.

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In some situations, members of the research team may not be fluent in English and/or do not have readily available internet access and therefore will not be able to complete online ethics training. In such situations, the IRB must approve an alternate human research education mechanism. Upon approval of such an exception, lead investigators will be asked to ensure that these members of the research team receive or have received alternate human research ethics training. Lead investigators must describe the alternate training in the application to the IRB.

4. Investigators Must Renew Ethics Training Every Five Years

5. Investigators Conducting Human Participant Research Must Submit a Descriptive Research Protocol to the RCO

The human participants research protocol must include:

- a) A description of the hypothesis and research methods,
- b) Adequate provisions to protect the privacy of participants and to maintain the confidentiality of data,
- c) An informed consent or a request for waiver of informed consent,
- d) The Curriculum Vitae of the lead investigator(s),
- e) Documentation of ethics training of all investigators, and
- f) The signature of the lead investigator(s), the department chair, and, if the researcher is a student, the signature of the faculty advisor.

6. Students Conducting Human Participants Research Must Obtain IRB Approval for Certain Research

Examples include but are not limited to, an Independent Study Class, an Honors thesis or a Graduate School thesis.

IRB review is not required for students completing human participant research as a part of a regularly scheduled class unless the research will be presented at a conference or in a published article.

7. IRB Determines the Level of Review of Human Research Protocols

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

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8. IRB Reviews all Research Protocols Involving Human Participants

The IRB must review all research protocols involving human participants in order to confirm:

- a) Risks to participants are minimized,
- b) Risks to participants are reasonable in relation to anticipated benefits to participants, if any, and the importance of knowledge that may reasonably be expected,
- c) Selection of participants 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) Participants are adequately informed of their rights and informed consent are documented,
- e) Data obtained from the research are maintained in manner that protects the confidentiality of the data and the privacy of the participants, and
- f) Where participants 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 participants.

9. Investigators Must Obtain Informed Consent from Research Participants

Investigators must obtain written acknowledgment that the participants 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. Waivers or consent alterations may be available under the following circumstances:

- a) The research involves no more than minimal risk to the research participants.
- b) The waiver or alteration will not adversely affect the rights and welfare of the participants.
- c) The research could not practicably be carried out without the waiver or alteration.
- d) Whenever appropriate, the participants will be provided with additional pertinent information after participation. 45 CFR 46.§116(d)

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10. **Investigator(s) Must Comply with Record Retention Rules**

Investigators must retain data and informed consents from all research participants for six years following the completion of the data collection.

11. **Participants Must Retain Data for Six Years Following the Completion of the Data Collection**

12. **Investigator(s) Must Report Certain Issues**

Investigators must report the following to RSP:

- 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 Human Participants Research Policy May Constitute Research Misconduct Under University Policy**
[POL-U4520.02 Addressing Responsible Conduct of Research](#)