

Research Involving Human Subjects

POLICIES

Faculty, staff, and students conducting research activities at Washington State University that involve human subjects must comply with federal, state, and University policies.

The overall intent of the policies described in this section is to:

- Ensure that human participants are protected.
- Ensure that human participants are treated physically, psychologically, and socially in such a way as to minimize embarrassment and stress.
- Avoid harm or other negative effects to human participants.

In addition to faculty and staff obligations, departments are responsible for ensuring that students who use data gathered from human subjects for theses and dissertations are fully informed of and comply with University policies.

RESEARCH PROJECT REVIEW

Federal, state, and University policies require the review of *all research projects using human subjects* conducted by faculty, staff, and students. This requirement applies to qualitative and quantitative research activities.

Institutional Review Board (IRB) Approval

Prior to initiating any portion of research projects involving human subjects, researchers must submit applications to the Office of Research Assurances (ORA) and receive approval from the University's Institutional Review Board (IRB).

Research projects involving human subjects are either considered to be non-exempt (subject to all federal rules, including those regarding application renewal review) or exempt (see Exempt Research). ORA personnel evaluate applications for determination of exempt status.

Research projects involving more than minimal risks to human subjects are recommended for review by a quorum of the entire convened IRB. Such review is referred to as full-board review.

Research projects involving no more than minimal risk to human subjects may be reviewed by one or two members designated by the IRB chair, rather than by the full board. Such review is referred to as expedited review.

Non-Exempt Research

IRB approval of expedited and full-board applications for non-exempt research projects involving human subjects is valid for a maximum of *one* year. If a non-exempt research project lasts

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Non-Exempt Research (cont.)	longer than one year, the researchers must submit an annual application to the IRB for renewed approval (also referred to as continuing review).
<i>Amendment Review</i>	The IRB must review and approve all amendments to currently approved non-exempt research projects prior to implementation.
Exempt Research	<p>Research activities may be considered exempt if the involvement of human subjects is limited to one of the categories 1-6 listed in 45 <i>CFR</i> 46.101(b), including studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable. Contact the ORA for further information.</p> <p>Researchers conducting research activities that are exempt must submit initial applications for review and certification to the ORA. However, continuing review is not required for exempt research activities.</p>
<i>Amendment Review</i>	The IRB must review and approve all amendments to currently certified exempt research projects prior to implementation.
Student Research	Departments and advisors are responsible for ensuring that students comply with University review procedures. Student failure to comply with University review procedures may make it impossible for the Graduate School to accept theses or dissertations involving human subjects research.

TRAINING

Non-Exempt Research	<p>All principal investigators for non-exempt research projects must complete human subjects training prior to (or concurrent with) submitting human subject research applications to the IRB. In addition, non-exempt research project principal investigators are required to complete refresher training every five years.</p> <p>The principal investigators must ensure that other personnel involved with non-exempt human subjects projects complete the training.</p>
Exempt Research	The ORA highly recommends that principal investigators for exempt research projects complete human subjects training prior to (or concurrent with) submitting human subject research applications to the IRB.

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- Exempt Research (cont.)** The ORA recommends that principal investigators ensure that other personnel involved with exempt human subjects projects complete the training.
- Training Materials** The University's IRB utilizes Collaborative Institutional Training Initiative (CITI) human subjects education. University faculty, staff, and students may access CITI training materials from the IRB website at:
- www.irb.wsu.edu/
- Additional Resources**
- IRB Handbook** The WSU IRB Handbook contains information and requirements regarding the conduct of research involving human subjects and activities of the IRB. The handbook is available from the IRB website at:
- www.irb.wsu.edu/
- Application Forms** IRB application forms are available from the IRB website at:
- www.irb.wsu.edu/forms.asp
- Assistance** For questions, contact the Office of Research Assurances; telephone 509-335-3668; or e-mail to irb@wsu.edu.