

**Does your research require
Washington State University Institutional Review
Board's (WSU IRB) Review and Approval?**

Does your study involve **human subjects**¹ and is it a **research**² activity?

If you answer yes and if you:

- work for WSU, at the Pullman or other urban campuses,
- a satellite facility,
- a cooperative unit

then, WSU IRB's review and approval is required **prior to subject recruitment or data collection.**

According to WSU research policy, all research conducted with human subjects in WSU should be in adherence to regulations, rules, policies, and guidelines regardless of the funding source.

A wide spectrum research areas involving human subjects have federal, state, local and Institutional guidelines to protect human subject participants.

Some examples of human subject research includes but not limited to surveys, observation, interviews, accessing private records, *taste testing*, clinical trials, therapeutic evaluations,

¹ A 'human subject' is a living individual about whom an investigator indirectly or directly obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information (as per Title 45 Code of Federal Regulations, Part 46, June 18, 1991).

² Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of the WSU IRB, 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.

experimental treatments, bodily materials, residual diagnostic specimens, cell lines or DNA samples etc.,

Studies with vulnerable populations

Federal, state and WSU guidelines provide special protection for populations falling under the following categories:

- Select Native American tribes
- Substance abusers
- Non-English speaking population(s)
- Children, prisoners, pregnant women, or fetus

WSU IRB must review and approve research if it involves interactions with one of these populations, either directly or indirectly. For a complete list of vulnerable populations visit- www.irb.wsu.edu

About WSU IRB

The WSU IRB is a presidential committee with board members of various technical expertise, administrators and community members who review minimal risk to high risk research protocols submitted by investigators.

Specifically: 1) the IRB members review research protocols to determine and certify that the protocols conform to the regulations and policies set forth by the federal agencies, in particular by the Department of Health and Human Services (DHHS) regarding the health, welfare, safety, rights, and privileges of human subjects; and 2) assist investigators in conducting ethical research which complies with the DHHS regulations in a manner that facilitates accomplishment of the research activity.

Types of IRB review

An IRB application submitted for review will fall into one of the following categories listed below. The categories reflect the risks for the human subjects participating in the study.

Full board Review- Studies that involve more than minimal risk are recommended for review by a full board. Approval for these studies requires that the proposed research be reviewed at a convened meeting with a quorum of IRB members present. IRB approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

Expedited Review- Certain kinds of research involve no more than minimal risk and for minor changes in approved research. These will be reviewed by one or two members designated by the IRB chair rather than by the entire convened IRB. Approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

Exemption- Any research study considered as minimal risk to human subjects can be exempt under federal regulations; however the exempt form must be submitted to the IRB for a determination. The exempt categories include certain educational practices and tests, study of archived or existing data, public service programs and *food evaluation*. No renewals are required for a certified exempt project, although amendments are required to be submitted for determination of exemption by IRB.

Adverse events in all studies should be promptly reported to WSU IRB at 509-335-3668 or by email at irb@wsu.edu.

Application process for WSU IRB

Application materials for review by IRB can be found at www.irb.wsu.edu/forms. Completed applications should be submitted to IRB office. The contact details are provided in the front page of this brochure.

Approximate Timeline for IRB Review

Applications to WSU IRB are reviewed under one of the following categories:

Review Category	Time
Exempt	10 working days*
Expedited	12 working days*
Full Board	At monthly IRB meeting

* from the date of receipt, excludes holidays and weekends.

Given the time frame for approval it is essential to plan a study well ahead of time. **A study can begin only after the IRB has formally approved the application.**

Informed Consent

Potential subjects participating in research must be adequately informed about the key aspects of research study. This information is provided by the use of informed consent. After all the relevant details regarding the study has been provided to the participants, their participation in research should be voluntary. An ideal informed consent should have the following items:

- Purpose of research
- Benefits of research to the society
- Procedures involved in research
- Alternatives available if subject decides not to participate
- Risks and discomforts to the subjects including physical injury, possible psychological, social, or economic harm, discomfort, or inconvenience

- Length of time the subject has to participate
 - Contact person in case of injury and illness due to participating in the study
 - Statement that participation is *voluntary*
 - Clarify the subject's *right to confidentially* and *right to withdraw*
- Complete guidelines and sample templates of informed consent can be obtained from: www.irb.wsu.edu

Research with *children* requires parental permission and assent forms for minors.

CITI Training

WSU IRB requires all PIs to complete human subject training when working with human subjects and submit expedited and full board review applications. However PIs on exempt applications are highly recommended to complete the CITI training. It is the responsibility of the PI to ensure that all personnel on the project have received appropriate and continued training, as necessary.

WSU IRB provides online training for PI and Co-PIs through the Collaborative Institutional Training Initiative (CITI) program. The researchers are encouraged to select the appropriate optional module that addresses the areas of research along with required modules. Visit: www.irb.wsu.edu/ for further details about CITI training. Retraining is necessary every five years.

IMPORTANT

IRB only approves research activities related to human subjects. If you are working with biological agents, or animals, you will need approval from other committees. Visit: www.ora.wsu.edu for further details.

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Does your Research involve Human Subjects?

.....This brochure will provide basic information to ensure that your research is compliant with federal, state regulations and WSU guidelines.

WSU Institutional Review Board



Office of Research Assurances
Neil 427
P.O. Box 643143
Pullman, WA 99164-3143
Phone: (509) 335-3668
Fax: (509) 335-6410
www.irb.wsu.edu
irb@wsu.edu

Working with Researchers to Minimize Research Risks on Human Subjects