Research Involving Human Subjects

POLICIES

Research activities at Washington State University that involve human subjects must comply with federal and state statutes, regulations, and ethical principles, and University policies. This section provides an overview of the oversight and requirements related to human subject research activities at WSU.

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

- Minimize potential risks to human participants in WSU research;
- Minimize risks to others (e.g. University employees, students and the general public);
- Ensure that potential risks are reasonable in relation to potential benefits and;
- Ensure the public’s trust in Washington State University.

Institutional Review Board (IRB)

The Institutional Review Board (IRB) is a Washington State University (WSU) presidential committee charged with protecting the rights and welfare of participants involved in human subject research. The IRB ensures that participants are treated physically, psychologically, and socially in such a way as to minimize the potential for physical and emotional harm or other negative effects associated with participation in human subject research.

In fulfillment of this mission, the IRB is guided by:

- Federal and state statutes and regulations;
- University policies; and

The WSU IRB functions independently and reports directly to the President; however, reporting is usually facilitated through the Vice President for Research. The IRB is part of the WSU Human Research Protection Program (HRPP) and is supported by HRPP and IRB Office staff within the Office of Research Assurances (ORA).
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IRB (cont.)

The Vice President for Research:

- Is the legally authorized institutional official (IO);
- Is the signatory official on the WSU Federal-wide Assurance (FWA) agreement with the United States Department of Health and Human Services (HHS);
- Has operational authority over the HRPP; and
- May delegate this authority to qualified individuals in the Office of Research (OR), ORA, and the HRPP.

The OR, ORA and the HRPP have operational authority to develop and implement the subordinate policies and standard operating procedures, including the IRB Policies and Procedures Manual, that outline IRB committee and office functions necessary to implement this policy.

Statutes, Regulations, Policies, and Ethical Principles

In compliance with the terms of the WSU FWA to the HHS, when the institution is engaged in human subjects research conducted or supported by any U.S. federal department or agency the WSU IRB and HRPP are guided by the:

- U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule); and
- Ethical principles outlined in the Belmont Report.

When the institution is engaged in human subject research that is not covered by the terms of the FWA, the WSU HRPP ensures the application of equivalent protections as outlined in the Belmont Report.

Compliance Responsibilities

All faculty, staff, volunteers, visiting scholars, and students (anyone acting as an agent of WSU) conducting research activities at WSU that involve human subjects must comply with federal and state statutes and regulations, and University policies.

Principal investigators and 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. See also Training below.
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APPOINTMENT AUTHORIT Y/TERMS AND IRB COMPOSITION

IRB members are appointed by the President; however, appointment authority is normally delegated to the Vice President for Research. When authority is delegated, it is done in writing naming the individual or position with appointing authority. Appointment authority remains in effect until revoked in writing by the President or until the end of the term specifically designated.

Members, including chairs, are generally appointed for terms of one to three years. However, members appointed mid-year may have varied terms of appointment. Some members may receive ex-officio appointments that are linked to their positions at WSU. The terms of appointment, including voting or alternate status and member expectations, are to be outlined in the member appointment letter.

NOTE: Attorneys from the Attorney General's Office, WSU Division, attend and participate in IRB meetings solely as legal advisors.

WSU Institutional Review Board(s) must each consist of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. IRB(s) must be sufficiently qualified through the experience and expertise (i.e., professional competence) and the diversity of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. For purposes of IRB membership, diversity of members includes race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes.

Membership is to include, but not be limited to the following:

• At least one member whose primary concerns are in scientific areas.

• At least one member whose primary concerns are in nonscientific areas.

• At least one member who is not otherwise affiliated with the University.

• At least one physician (when reviewing research covered by FDA regulations or involving the conduct of clinical trials or clinical research in a biomedical setting).
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IRB COMPOSITION (cont.)

• Individuals who are knowledgeable and experienced in working with vulnerable categories of subjects such as children, prisoners, cognitively impaired persons (individuals unable to consent on their own behalf), or pregnant women.

• IRB membership will consist predominantly of faculty but may be supplemented by staff and students.

• No member may participate in the initial or continuing review of any project in which that member has a conflicting interest (financial or otherwise), except to provide information requested by the IRB. See Executive Policy Manual EP27 and the IRB Policies and Procedures Manual Section 105.

• The WSU IRBs may, at their discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRBs. These individuals may not vote with the IRBs.

RESEARCH PROJECT REVIEW

Institutional Review Board (IRB) Approval

Prior to initiating any portion of research projects involving human subjects, researchers must submit applications to the ORA and receive approval from the University's IRB.

When a project involves multiple institutions/organizations, WSU attempts to enter into cooperative agreements or reliance agreements to minimize the need for concurrent review. Such agreements are also referred to as either institutional authorization agreements (IAAs) or individual investigator agreements (IIAs). The procedures for establishing these agreements are described in subordinate policies. Contact the HRPP office for more information.

Research projects involving human subjects are either considered to be non-exempt or exempt. Non-exempt research is subject to all federal, state, and funding agency rules when federally funded and is subject to equivalent protections under WSU policy when not federally funded. Exempt research is subject to WSU policies that require ethical conduct of research (see Belmont Report). Qualified ORA personnel, faculty reviewers designated by the HRPP, or IRB members evaluate applications for determination of exempt status.
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<tr>
<th>IRB Approval (cont.)</th>
<th>Certain research projects involving no more than minimal risk to human subjects may be reviewed by one or two members designated by the IRB chair, or a designee with appropriate training and experience (e.g. IRB/HRPP staff), rather than by the full board. Such review is referred to as expedited review.</th>
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<tr>
<td>Research projects that are not eligible for expedited review, or that potentially involve more than minimal risk to participants are reviewed by a quorum of the convened IRB. Such review is referred to as full-board review.</td>
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**Amendment Review**

The IRB must review and approve all amendments to currently approved non-exempt research projects prior to implementation. Review of non-substantive changes to a protocol may be delegated to qualified individuals by the IRB (administrative review).

**IRB Review Outcomes**

When reviewing a research project, the IRB has the authority to:

- Approve;
- Require modifications to secure approval;
- Disapprove any research project involving human subjects; and/or
- Suspend or terminate approval of any research project that is not conducted in accordance with IRB approval.

**Temporary Pause**

The Vice President for Research, IRB Chair, Director of the Office of Research Assurances, or Assistant Director of the Human Research Protection Program have the authority to temporarily pause any research project:

- Where an adverse event or alleged noncompliance has occurred; **and**
- When there is reason to believe that continuation of the research may lead to:
  - Further harm of research participants or others; or
  - Continuing noncompliance.
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Investigation

When a research project is paused, it must not resume until such a time as the IRB can be convened to investigate and determines that it is safe to resume.

NOTE: Any project that is disapproved by the IRB may not be approved by the institution. However, a project that is approved by the IRB may be subject to approval by other oversight committees and is potentially subject to disapproval by the University.


The IRB Policies and Procedures Manual, which is incorporated herein by reference, contains detailed procedures for the handling of investigations and required reporting of:

- Deviations;
- Noncompliance;
- Adverse events; and
- Unanticipated problems involving risks to subjects or others (UPIRSOs).

Non-Exempt Research Approval Periods and Continuing Review

IRB approval of expedited and full-board applications for non-exempt research projects is valid for a maximum of one year. If a non-exempt research project lasts longer than one year, the researchers must submit an annual status update when continuing review is not required as a determination of the IRB. See the IRB Policies and Procedures Manual for details regarding continuing review and status report requirements.

Exempt Research

Research activities may be considered exempt if the involvement of human subjects is limited to one of the categories listed in 45 CFR 46.104(d)(1)-(8), including, but not limited to studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable.

Research falling under some exempt categories (e.g. categories 7-8 or minimal risk flex categories when not federally funded) is rare at WSU and requires specific institutional approval.

Researchers conducting research activities that are exempt must submit initial applications for review and certification to the HRPP (ORA/IRB Office). However, continuing review is not required for exempt research activities.
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**Amendment Review**

The IRB or HRPP staff must review and approve all amendments to currently certified exempt research projects prior to implementation to ensure that the project still qualifies for exemption.

**HIPAA Privacy Review**

The WSU IRB is the acting Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Board. The University may at any time appoint an alternative acting or permanent HIPAA Privacy Board. When an alternate privacy board is named, the IRB is to be kept informed of any decisions rendered that may impact the conduct of human subject research.

Board members must receive training regarding HIPAA and the responsibilities as the acting privacy board. Training requirements are established by the acting HIPAA Privacy Officer or HIPAA Security Officer and are facilitated by the University office designated by these officers.

**Other Regulatory Reviews and Non-Regulatory Ethics Reviews**

The HRPP may be called upon by the University to conduct regulatory or ethics reviews or risk assessments of projects that do not meet the HHS regulatory definitions requiring IRB review.

When this occurs, the HRPP follows the general procedures outlined for project review in the *IRB Policies and Procedures Manual* or develops alternative written procedures for these reviews.

**Other Privacy/Data Security Reviews**

Other privacy and/or data security reviews which do not meet the HHS regulatory definitions requiring IRB review include, but are not limited to, reviews which fall under the following:

- Family Educational Rights and Privacy Act (FERPA);
- Protection of Pupils Rights Amendment (PPRA);
- Confidentiality of Substance Use Disorder Patient Records (SUD), 42 CFR Part 2;
- National Institutes of Health Genomic Data Sharing (NIH GDS) Policy.

**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
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Student Research (cont.) impossible for the Graduate School to accept theses or dissertations involving human subjects research.

TRAINING

Non-Exempt Research All principal investigators and key personnel involved in 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.

The principal investigators are responsible for ensuring that other personnel (co-investigators and other research personnel, including students) involved with non-exempt projects complete all required training prior to (or concurrent with) submitting human subject research applications to the IRB.

Exempt Research The HRPP requires the completion of human subjects research training for principal investigators, co-investigators, and other research personnel (including students) who are to directly interact with research participants (or their identifiable biospecimens or information) during the conduct of exempt research. The HRPP highly recommends this training for all personnel involved in these projects.

Training Materials The University's IRB utilizes Collaborative Institutional Training Initiative (CITI) human subjects education. University faculty, staff, and students may access the CITI web platform and related training materials from the IRB website at:

irb.wsu.edu/

NOTE: In addition to HRPP/IRB required training offered through CITI, WSU also requires responsible conduct of research (RCR) and conflict of interest (COI) training for most WSU research personnel.

Refer to the Office of Research Policies website for an overview list of policies and guidelines related to the conduct of research:

research.wsu.edu/office-research/policies/
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**Application Forms and Additional Resources**
The WSU IRB website contains all required application forms and information, including policies, procedures, and guidance documents, regarding the conduct of research involving human subjects and activities of the IRB. See:

irb.wsu.edu/

**Assistance**
For questions, contact the Human Research Protection Program, Office of Research Assurances; telephone 509-335-7646; e-mail irb@wsu.edu or ora.hrrp@wsu.edu.