Overview of the Office of Research Assurances (ORA)

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ENSURING SAFE, COMPLIANT, AND ETHICAL RESEARCH

The Office of Research Assurances (ORA) fosters responsible research practices.
Overview of ORA

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ora.wsu.edu
Introduction

• ORA (est. 2002) is part of the overall effort of WSU to ensure responsible conduct of research.
• We work collaboratively with researchers and staff to stay in compliance with applicable internal and external policies and regulations.
• By staying in compliance we avoid funding delays, funding denials, unpublished research, and - in some cases fines - jail.

Our philosophy is centered on customer service and helping PI’s and departments navigate the labyrinth of laws and policies that affect research at WSU.
Institutional Animal Care and Use Committee (IACUC)

Who Oversees Animal Welfare?

USDA

Office of Laboratory Animal Welfare (OLAW)

National Institutes of Health (NIH)

BPPM/SPPM

Office of the Campus Veterinarian

Animal Welfare Program

WAC

iacuc.wsu.edu
Institutional Animal Care and Use Committee (IACUC)

The IACUC provides **oversight of animals and animal care personnel** involved in research, teaching, and clinical education by ensuring that animal use is well-justified, designed to minimize discomfort or pain in animals, and is guided by scientific and educational relevance to human or animal health. To accomplish these goals, the IACUC...

- ensures animal welfare;
- provides training requirements - Principles of Animal Care & Occupational Health Training with Animals;
- is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC); and
- strictly follows the Guide for the Care and Use of Laboratory Animals.

**Replacement Reduction Refinement**

iacuc.wsu.edu
Institutional Biosafety Committee (IBC)

Who Oversees Research With Biological Materials?

Research Safety Program

Biosafety Officer & team

biosafety.wsu.edu
Institutional Biosafety Committee (IBC)

The IBC Reviews procedures for working with potentially hazardous biological materials including used in research:

- Genetically Modified Organisms (GMOs)
- Infectious Agents and Pathogens
  - Human
  - Animal
  - Plants
  - Environment
- Human Tissue and Cells

The IBC verifies containment practices & facilities

- Biosafety levels (BSL-1, -2, -3)

biosafety.wsu.edu
Institutional Review Board (IRB)

Who Oversees Human Subjects Research?

Office for Human Research Protections

U.S. Food and Drug Administration

BPPM/SPPM

Human Research Protection Program

WAC

irb.wsu.edu
The Institutional Review Board (IRB) is responsible for the review and approval of all research activities involving human subjects.

The IRB protects the rights and welfare of human subjects to ensure that all are treated in such a way as to minimize risk and avoid harm.

The guiding principles of the IRB are:

Respect for Persons
Beneficence
Justice
Radiation Safety Committee (RSC)

Who Oversees Radiation Safety?

Washington State Department of Health

BPPM/SPPM

United States Nuclear Regulatory Commission

WAC

Research Safety Program
Radiation Safety Officer & team

rso.wsu.edu
The WSU Radiation Safety Office team and Radiation Safety Committee ensures the **safe use of radioactive materials** and **radiation machines**.
Radiation Safety Committee (RSC)

With the oversight and direction of the Radiation Safety Committee (RSC), the WSU Radiation Safety Program supports the University's teaching, research and outreach mission by administering a program that ensures the secure and safe use, transport and disposal of radioactive materials and radiation machines by...

• reviewing procedures involving work with radioactive materials;
• addressing training requirements;
• monitoring radiation exposure of personnel;
• inventory and tracking radioactive materials;
• Managing radioactive waste disposal; and
• auditing labs for procedures, documentation, and properly working equipment.

rso.wsu.edu
WSU has recently organized the Safety, Health, and Security committees, into a 4 level hierarchy. Together, the committees engage and coordinate WSU administrators, campuses, colleges, departments, programs, students, and employees to sustain and improve WSU’s commitment to safety and a culture that emphasizes safety.
Export Controls

Who Oversees Export Controls?

These complex regulations govern:

1. The release of technology, technical data, & software to foreign nationals
2. The furnishing of defense services to foreign persons
3. The shipment or other transmission of items or defense articles outside the U.S.
4. The ability to transact with certain individuals, countries, & entities.

ora.wsu.edu/export-controls
Responsibilities of PIs:
It is ultimately each individual's obligation to comply with Export Control laws. Review research in advance for potential Export Control restrictions.
• If a license is needed, apply BEFORE the project begins—license approvals take 3-6 months or longer.
  • In general, delivery of services to an embargoed country (e.g., Cuba, Iran, North Korea, Sudan, or Syria) is not allowed without a license.
Hazardous Materials Shipping (HMS)

Who Oversees the shipment of hazardous materials?

Is my shipment (potentially) hazardous?

[Images of transportation modes: truck and airplane]

ora.wsu.edu/what-is-a-hazardous-material
Hazardous Materials Shipping (HMS)

Is my shipment (potentially) hazardous?

- Dry Ice
- Laboratory Chemicals (including preservatives)
- Pathogens
- Animal or Human specimens
- Compressed gas cylinders
- Lithium Batteries (in & out of equipment)
- GMO’s
- Radioactive materials

If your material is hazardous or you are not sure please call:

ORA Hazmat Shipping 509-432-3869

ora.wsu.edu/what-is-a-hazardous-material
Hazardous Materials Shipping (HMS)

WSU Hazmat shipping procedure:

1) ORA will process and ship all WSU hazmat shipments
2) Contact the hazmat shipping coordinator at (509) 432-3869
3) We will come directly to your location and collect your shipment
4) You will need to supply a completed Request for Shipment of Merchandise Form along with your shipment
5) ORA will generate a shipping label & verify that the contents are packaged and labeled according to the shipping regulations

All Hazmat shippers must be trained and certified per 49CFR Part 172

*If an individual knowingly or willfully violates a hazardous material shipping regulation this is considered to be a criminal violation.

ora.wsu.edu/what-is-a-hazardous-material
Who Oversees RCR?

Other funding agencies & professional organizations

Research Safety Program
Principal Investigators
Ultimately, everyone involved in research
Responsible Conduct of Research (RCR)

RCR training is available on MyResearch for Faculty, staff, & students (anyone credited on a grant must have current training).

Retraining is required every 5 years, which covers:

1. Data Acquisition, Management, Sharing and Ownership
2. Use of Humans
3. Conflict of Interest and Commitment
4. Use of Animals
5. Research Misconduct
6. Publishing Practices and Authorship
7. Mentor/Trainee Relationships and Responsibilities
8. Peer Review
9. Collaborations
Conflict of Interest (COI)

Who Oversees the Conflict of Interest?

Other funding agencies & professional organizations

COI is administered by the Office of Research Support & Operations (ORSO)

research.wsu.edu/resources-researchers/operations-support/coi
Conflict of Interest (COI)

The Conflict Of Interest Committee
- increases accountability;
- adds transparency; and
- enhances regulatory compliance.

The committee
- provides a COI application & management plan, and
- reviews all pertinent documentation to
  - assess whether a potential conflict exists;
  - assess the extent of the conflict; and
  - manage, reduce, or eliminate the conflict before approval.

WSU wants to manage conflicts and potential conflicts in order to support entrepreneurship while protecting the reputation of WSU and its PI’s.

research.wsu.edu/resources-researchers/operations-support/coi
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ora.wsu.edu

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