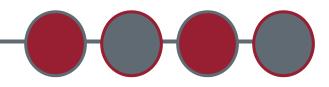




Office of Research Assurances





Overview of the Office of Research Assurances (ORA)

Levi O'Loughlin, PhD Assistant Director, Biosafety Officer Research Safety Program





Office of Research Assurances

ora.wsu.edu



OFFICE OF RESEARCH ASSURANCES | WSU









Office of Research Assurances

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Office of Research









mvWSU ACCESS POLICIES ©

OFFICE OF RESEARCH ASSURANCES

ENSURING SAFE, COMPLIANT, AND ETHICAL RESEARCH

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





Overview of ORA

- 1. Introduction
- 2. Institutional Animal Care and Use Committee (IACUC)
- 3. Institutional Biosafety Committee (IBC)
- 4. Institutional Review Board (IRB)
- 5. Radiation Safety Committee (**RSC**)
- 6. Export Controls
- 7. Hazardous Materials Shipping (HMS)
- 8. Responsible Conduct of Research (RCR)
- 9. Conflict of Interest Committee (COI)
- 10.Contacts





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- By staying in compliance we avoid funding delays, funding denials, unpublished research, and - in some cases fines - jail.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?













Animal Welfare Program



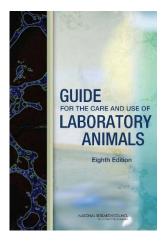
iacuc.wsu.edu



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



Institutional Biosafety Committee (IBC)

Who Oversees Research With Biological Materials?















Research Safety Program

Biosafety Officer & team





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







Institutional Review Board (IRB)

Who Oversees Human Subjects Research?













Human Research Protection Program





Institutional Review Board (IRB)

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?



Research Safety Program
Radiation Safety Officer & team







Radiation Safety Committee (RSC)

The WSU Radiation Safety Office team and Radiation Safety Committee ensures the **safe use of radioactive** materials and radiation machines.



As Low As Reasonably Achieveable



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.

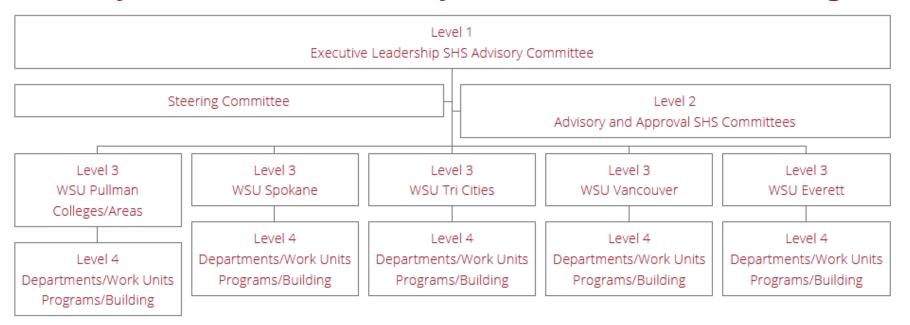
rso.wsu.edu







Safety, Health, and Security Committees and Meetings



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.



Export Controls

Most research activities at WSU are **exempted** from the E.C. regulations through the **Fundamental Research Exemption**.



Responsibilities of PIs:

It is ultimately each individuals 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?





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



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 <u>must</u> 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.



Responsible Conduct of Research (RCR)

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
- Use of Humans
- Conflict of Interest and Commitment
- Use of Animals
- Research Misconduct
- 6. Publishing Practices and Authorship
- Mentor/Trainee Relationships and Responsibilities
- 8. Peer Review
- Collaborations





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Conflict of Interest (COI)

Who Oversees the Conflict of Interest?







Other funding agencies & professional organizations



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



Conflict of Interest (COI)

The Conflict Of Interest Committee

- increases accountability;
- adds transparency; and
- enhances regulatory compliance.



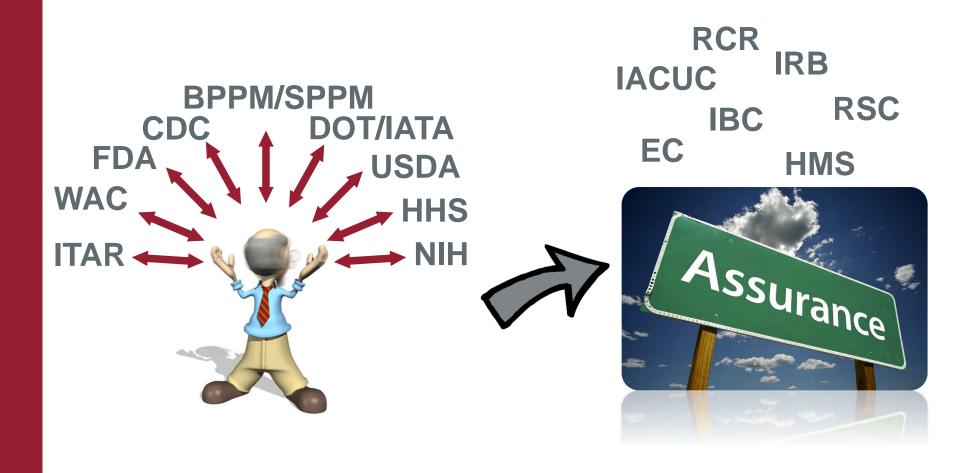
The committee

- 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 Pl's.



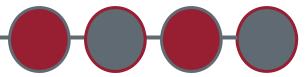
Office of Research Assurances





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ora.wsu.edu



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