


Introduction


- ORA, established in 2002, is part of the overall effort of WSU to ensure the responsible conduct of research.
- We work collaboratively with researchers 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- By staying in compliance we avoid funding delays, funding denials, unpublished research, and in some cases fines and jail.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.



Mission and Goals

Institutional Animal Care and Use Committee (IACUC)



IACUC

Who Oversees Animal Research?

- **USDA** U.S. Department of Agriculture
- **NIH** National Institutes of Health
- **OLAW** Office of Lab Animal Welfare
- **OCV** Office of the Campus Vet (WSU)
- **AWP** Animal Welfare Program
- **IACUC**

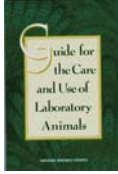



IACUC

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...

- provides training requirements;
 - Animal Awareness Seminars and the Animal Contact Program
- review procedures that use animals;
- address occupational health requirements; and
- minimizes ethical cost by following:

Replacement
Reduction
Refinement

Animals can be used safely and humanely in research

Institutional Biosafety Committee (IBC)



IBC


Who Oversees Research With Biological Materials?

- **NIH** National Institutes of Health
- **USDA** U.S. Department of Agriculture
 - **APHIS** Animal and Plant Health Inspection Service
- **BSO** Biosafety Officer (Local - WSU's ORA)
- **IBC**



Institutional Biosafety Committee (IBC)

- The IBC is a presidential committee charged to review, monitor, and ensure adequate containment of all infectious or potentially infectious agents (*i.e.* pathogens), toxins, or organisms with recombinant or synthetic nucleic acids (r/sNA).
- All research with these biological materials at WSU is reviewed to protect the research staff, investigators, the public, and the environment.




IBC

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

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


The IBC verifies containment practices and facilities

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




<https://biosafety.wsu.edu/>

Institutional Review Board (IRB)



US National Research Act 1974

- Established National Commission for Protection of Human Subjects
 - The Belmont Report, 1979
- Code of Federal Regulations, 1981
 - Institutional Review Boards (IRBs)
 - Informed Consent
- Common Rule (45 CFR Part 46), 1991
- HIPAA Privacy Rule (45 CFR Parts 160, 162, & 164), 2003



IRB

Who Oversees Human Subjects Research?


HHS U.S. Department of Health and Human Services

- OHRP Office for Human Research Protections

FDA U.S. Food and Drug Administration

HRPP Human Research Protection Program

IRB



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

Institutional Review Board (IRB)

Research involving humans has many benefits for society and is often a necessary component of research. Research involving human subjects has many specific requirements.

IRB review and approval

- Peer review committee, made up of faculty and administrators with expertise in a wide range of research.
- Research Protocols are submitted, reviewed, and returned for corrections or approved.
- Through this process:
 - Risks to subjects are minimized;
 - Quality Informed consent documents are generated; and
 - Education/Training of researchers;

<http://www.irb.wsu.edu>


Upcoming changes to Human Subjects Regulations and Policies

- The Federal Policy for the protection of Human Subjects in research is known as 'Common Rule'.
- In 2018, HHS made major revisions to the existing "Common Rule" regulations; those regulations are referred to as the Revised Common Rule.
- The general compliance date for the Revised Common Rule is *January 21, 2019*.

Significant Changes

- 'What is not research'- Clarified
- Exemptions are revised substantially.
- Changes to continuing reviews.
- ☐ No renewals required for exempt, expedited and certain more than minimal risk studies.
- ☐ However Annual Check-in will be implemented.
- Revisions on informed consent requirements
- Human Research Protection Program will provide:
 - Workshops
 - Help sessions
- Forms will be updated
- Questions, contact irb@wsu.edu or mjandyala@wsu.edu

Radiation Safety Committee (RSC)



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RSC

Who Oversees Radiation Safety?

NRC U.S. National Radioactivity Commission
DOH Washington Department of Health
RSP Radiation Safety Program
RSC




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RSC

The WSU Radiation Safety Program and Radiation Safety Committee ensures the safe use of radioactive materials and radiation machines on the Pullman campus and other WSU sites around the state.

As
Low
As
Reasonably
Achievable




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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.

<https://rso.wsu.edu/>



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Conflict of Interest (COI)



dreamstime.com

COI

Who Oversees Conflict of Interest?

- PHS U.S. Public Health Service
- NSF National Science Foundation
- FDA U.S. Food and Drug Administration
- Other funding agencies & professional organizations

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

COI

The Conflict Of Interest Committee will...

- Increase accountability
- Add transparency
- Enhance regulatory compliance and effective administrative management of PI's financial conflicts of interest.

We want to manage conflicts and potential conflicts in order to support entrepreneurship while protecting the reputation of WSU and its PI's.

COI Committee

Reviews all pertinent documentation, including the COI application & management plan, relating to potential or actual Conflict of Interests.

The COI Committee has the responsibility to:

- assess whether a potential conflict exists
- assess the extent of the conflict and
- manage, reduce, or eliminate the conflict before approval

<https://research.wsu.edu/resources-researchers/operations-support/coi/>

Export Controls



<http://www.ora.wsu.edu/ExportControls>



Export Controls

U.S. Export Control laws are in place to protect national security and foreign policy.

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

Who Oversees Export Controls?

Regulation	Federal agency with oversight	Area of Oversight
ITAR	Dept of State, DDTC	Defense articles, services, and related technical data
EAR	Dept of Commerce, BIS	Dual use items
OFAC	Dept of Treasury, OFAC	Prohibits transactions w/ countries & individuals of concern

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 such as (Cuba, Iran, North Korea, Sudan, or Syria) is not allowed without a license.

Responsible Conduct of Research (RCR)



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RCR

Who Oversees RCR?

- State of Washington
- NIH/NSF
- Professional Organizations
- WSU V.P. for Research
 - Office of Research Assurances
- Principal Investigators
- Ultimately, everyone involved in research



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RCR

RCR training is available on MyResearch for Faculty, staff, & students.
Retraining is required every 5 years. Anyone who is credited on a grant must be current on training.

- 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



www.myresearch.wsu.edu

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Hazardous Materials Shipping (HMS)



<http://www.ora.wsu.edu/Shipping/>

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)

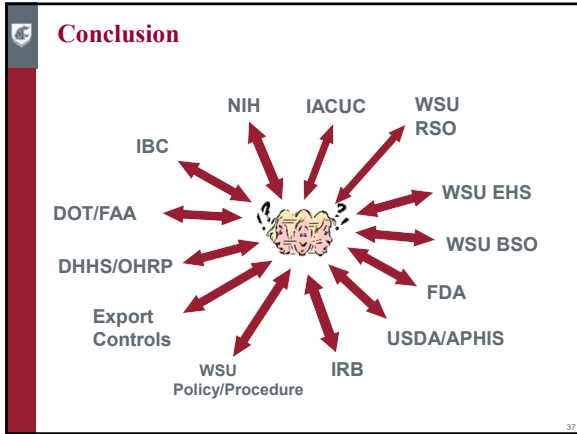
WSU Hazmat shipping procedure:

- 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 **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.





Office of Research Assurances
ora.wsu.edu

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