Office of Research Compliance

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Director, Office of Research Compliance
Office of Research Compliance Areas

- Biosafety
- Conflict of Interest
- IACUC
- IRB
- Radiation Safety
- Training
- Committees
- Additional Services
- Agreements
- Committees
- Export Control
- Responsible Conduct of Research
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Graduate Student Responsibilities

- Prior to initiating activity requiring research oversight:
  - Attend applicable training
    - Live training or online training through CITI Program
    - Training must be renewed in general every three years
Graduate Student Responsibilities

• During the conduct of research:
  – Adhere to the approved protocol and MSU policies
  – Report any adverse events, safety issues, or unanticipated problems
Biosafety

MSU Biosafety Website:
• http://www.montana.edu/orc/biosafety/index.html

MSU Biosafety Training website:
• http://www.montana.edu/orc/training/biosafety/index.html

MSU Biosafety Manuel:
• MSU Biosafety Manual

Regulations:
• BMBL 5th Edition (CDC)
• Bloodborne Pathogens Regulation (OSHA:1910:1030)
• NIH Recombinant and /or Synthetic Nucleic Acid Guidelines
• Select Agents (42CFR73)

Biosafety Program Mission Statement
The mission of the Biosafety Program at MSU is to ensure a safe environment for individuals working with biohazardous materials and to ensure the protection of the community and environment by preventing exposure to biohazardous materials. To accomplish this, the Biosafety Program provides technical advice to Principal Investigators on laboratory containment, security, and safety procedures.

Biosafety Officer
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Radiation Safety

MSU Radiation Website:
- http://www.montana.edu/orc/radiation/

MSU Radiation Safety Training Website:
- http://www.montana.edu/orc/training/radiation/index.html

MSU Radiation Safety Manual:
- MSU Radiation Safety Manual

Regulations:

Program Description

All uses of radioactive materials at Montana State University must be approved by the university’s Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO). Approvals for radioactive materials by the RSC are expressly for the protocols and personnel specified in the radioactive material application. Any unauthorized uses or materials constitutes a violation of University, State and Federal regulations.

In Montana, the Nuclear Regulatory Commission (NRC) determines safe practices for sources of radioactivity. NRC regulations on radioactive materials are published in Title 10 of the Code of Federal Regulations.

Proper management of radioactive materials and users is the responsibility of the authorized Principal User, under whose permit the device is being used. It is the responsibility of each member of the laboratory to maintain safe use of radioactive materials in their area.

Radiation Safety Officer
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Conflict of Interest

MSU Conflict of Interest Website:  
- http://www.montana.edu/orc/conflict-interest/index.html

MSU Conflict of Interest Training Website:  
- http://www.montana.edu/orc/training/citi/coi-training.html

State and University Policies:  
- MSU Conflict of Interest Policy
- Relationships in the Workplace
- MSU Consensual Relationship Policy (see 280.00)
- BOR Policy 770
- Montana Law, Standards of Conduct - Code of Ethics

Reporting and Forms:  
- New Disclosure Form
- Management Plans
- Annual Reporting
- Public Disclosure Guidance

The administration, faculty, and staff of the campuses of Montana State University all bear the responsibility of serving the respective teaching, research, and service missions of the campuses. That mission is enhanced by the sustained, active interaction of members of the University community with business, government, not-for-profit groups, professional societies, academic institutions, and other individuals and organizations. Therefore, entrepreneurial activities are encouraged that support the University’s mission through dissemination of knowledge, enhancement of educational opportunities for students, and economic development. These many interactions and activities can, however, create the potential for conflict of interest in which University employees’ external activities or interests could influence—or could appear to influence—the manner or extent to which those individuals carry out their University responsibilities. Such influences—real or apparent—may undermine public and professional confidence in the campuses, diminish the University’s ability to accomplish its mission, or violate state or federal law.

State and University Policy
- MSU Conflict of Interest Policy
- Relationships in the Workplace
- MSU Consensual Relationship Policy (see 280.00)
- BOR Policy 770
- Montana Law, Standards of Conduct - Code of Ethics

Reporting and Forms
- New Disclosure Form
- Management Plans
- Annual Reporting
- Public Disclosure Guidance

Federal Policy
- 42 CFR Part 5 Subpart F: Promoting Objectivity in Research
- 41 CFR Part 96: Responsible Prospective Contractors and Federal Sub
- NIST Regulations
- NSF Regulations

For MSU Employees:
- Equity Interest/Private Business Participation:
  - 455A.05.20.1589
  - Implemented by BOR Policy 457
  - 457 Application Form - Contact the ORC to complete and submit.
Responsible Conduct of Research

MSU RCR Website:
• http://www.montana.edu/orc/responsible-conduct.html

Training Requirements
• NSF RCR Training Requirements
• NIH RCR Training Requirements

Elective Training Opportunities
• Introduction to Responsible Conduct of Research
• Online Ethics Center For Engineering and Science
• David Mogk’s GeoEthics RCR Resources
It is the policy of Montana State University-Bozeman to require the highest ethical standards in the research of its faculty and staff; to inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged or apparent misconduct; and, as appropriate, to comply in a timely manner with requirements for reporting cases of possible misconduct to sponsoring agencies when sponsored research funds are involved. Misconduct in research shall be considered a breach of contract between the employee and the University.

Research Misconduct Policy

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Animal Care and Use

MSU IACUC Policies:
- http://www.montana.edu/orc/iacuc/policies.html

Guidelines:
- ARENA/OLAW IACUC Guidebook
- Fish Use Guidelines 2014
- Guide for the Care and Use of Laboratory Animals

MSU IACUC Website:
- http://www.montana.edu/orc/iacuc/index.html

MSU IACUC Training website:
- http://www.montana.edu/orc/training/citi/index.html

Committee Mission Statement
The University is committed to the responsible and ethical care and use of animals in research. The Institutional Animal Care and Use Committee ensures the health, well-being, and humane use of animals in research, following the regulations and guidance of the US Department of Agriculture and the Department of Health and Human Services.

Montana State University's Institutional Animal Care and Use Committee is responsible for reviewing all protocols involving live vertebrate animals for research, training, and testing, and ensures compliance with all applicable laws, policies, and federal regulations. The IACUC ensures that all animals are treated humanely and that research is performed to the highest standards. The IACUC is also responsible to review the program for humane care and use of animals, and to inspect all animal facilities (including satellite facilities) and laboratories, and oversee training and educational programs.

IACUC Resources
- Manuals
- Policies
- Protocol Review Check Sheet (Mice)
- Resources/Regulations

Direct Links
- Animal Care and Use Concern Form
- Adverse Event Form
- Fish Use Guidelines 2014
- Individual Qualification Training Form
- ASM Guidelines for the Use of Wild Mammals

Users Working With
- All Animal Users and PIs

Training
1. CITI training
   a. Animal Biosafety
   b. Investigators, Staff and Students
   c. Principal Investigators (if applicable)
   d. Species Specific Training
2. Animal Care at MSU (face to face)
   a. Introduction to Animal Care & Use at MSU
   b. Occupational Health and Safety
3. Occupational Health and Safety Clearance
   a. Completion of Risk Assessment
   b. Medical History/Animal Allergy
4. Protocol specific procedure training and assessment

IACUC & IBC Project Manager
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Export Control

MSU Export Control Manual:
- Export Control Manual

Resources:
- Technology Control Plan
- Export Control Review Form
- Federal Resources

MSU Export Control Website:
- http://www.montana.edu/orc/exportcontrol/index.html

Export Control Information
- Export Control Overview
- MSU Export Control Policy
- Violation Penalties

Frequently Asked Questions
- FAQ Page

Resources
- Export Control Manual
- Technology Control Plan
- Export Control Review Form
- Federal Resources

Export Control
Joe Brown
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Committee Mission Statement
The primary mission of the Institutional Review Board is the protection of the rights, welfare and wellbeing of human subjects who participate in research at Montana State University. We follow the ethical standards described in the Belmont Report, as well as all applicable federal, state and local regulations. In addition to those regulations, we abide by university policies and procedures.

MSU IRB Website:
• http://www.montana.edu/orc/irb/index.html

MSU IRB Training Website:
• http://www.montana.edu/orc/training/citi/index.html

MSU IRB Policies:
• IRB Operating Principles
• Reliance Agreements
• Types of Review
• Forms and Applications
• Guidelines (Consent / Risks)
• Additional Information
• Tribal College IRBs
• HIPAA

IRB Administrator
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Institutional Review Board