

Office of Research Compliance

Kirk Lubick
Director, Office of Research Compliance



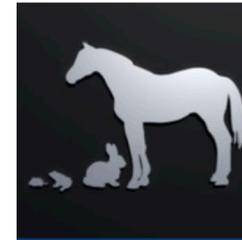
Office of Research Compliance Areas



Biosafety



Conflict of
Interest



IACUC



IRB



Radiation Safety



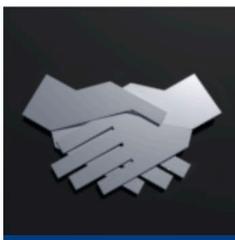
Training



Committees



Additional
Services



Agreements



Committees



Export Control



Responsible
Conduct of
Research

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Radiation Safety Officer

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Export Control

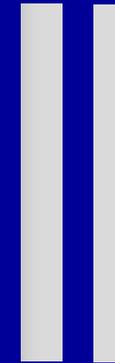
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Research Compliance Staff

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

So Many Rules to Follow



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 Manual:

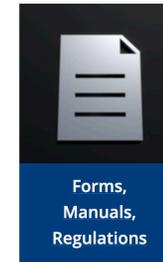
- [MSU Biosafety Manual](#)

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.



Forms,
Manuals,
Regulations



Pathogen Safety
Data Sheet



Policies



Biosafety
Training

Working With	CITI Training	2020 MSU Training Schedule
Biological Agents	Biosafety for BSL1 and BSL2 Laboratories	Biosafety & Chemical Safety Training
Human blood or Other Potentially Infectious materials	OSHA Bloodborne Pathogens	Biosafety & Chemical Safety Training
Recombinant or Synthetic Nucleic Acids	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids	Biosafety & Chemical Safety Training
Shipping Certification for Biological Agents	Shipping and Transport of Regulated Biological Materials	Shipping Biohazardous Materials

For Biosafety trainings taking either the On-Campus or the applicable CITI trainings will fulfill the requirement.

Biosafety Officer

Ryan Bartlett

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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:

- <http://www.nrc.gov/reading-rm/doc-collections/cfr/>
- <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>
- https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10098

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.



Working With	Training
Open or sealed source radioactive material	RAM training for laboratory workers
Open or sealed source radioactive material	RAM training for laboratory workers refresher
Sealed Ni-63 sources contained within electron capture devices	Ni-63 Electron Capture Device Training
Mossbauer (Fe-57) sealed sources	Mossbauer sealed source training
X-ray generating equipment (includes scanning electron microscopes)	X-ray safety training
Class 3B and 4 lasers	Laser safety training

Radiation Safety Officer

Nick Childs

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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.

<p>State and University Policy</p> <ul style="list-style-type: none"> 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 	<p>Federal Policy</p> <ul style="list-style-type: none"> 42 CFR Part 50 Subpart F: Promoting Objectivity in Research 45 CFR Part 94: Responsible Prospective Contractors and Financial COI NIH Regulations NSF Regulations
<p>Reporting and Forms</p> <ul style="list-style-type: none"> New Disclosure Form Management Plans Annual Reporting Public Disclosure Guidance 	<p>For MSU Inventors:</p> <p>Equity Interest/Private Business Participation:</p> <ul style="list-style-type: none"> • MCA 20-25-109 <ul style="list-style-type: none"> ◦ Implemented by BOR Policy 407 ◦ 407 Application Form - Contact the ORC to complete and submit.

Description	This training contains 4 required modules covering topics such as: commitment, conscience, and financial conflicts, institutional responsibilities, and institution-specific policies. An average score of 80% is needed to pass the training.
Completion Information	Upon completion of this training attendees will be allowed to conduct federally sponsored research.
Protocol Requirement	Not Applicable
Valid for	4 Years
Duration	About 1 hour
Course Materials	No materials are required.
Training Outcome	At the conclusion of the training attendees will know: <ul style="list-style-type: none"> • The major types of conflicts of interest • Your responsibilities for dealing with conflicts of interest • Institution-specific policies for conflicts of interest

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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](#)

Training: NSF vs. NIH RCR Requirements

NSF RCR training requirements differ from NIH training requirements in that NSF requires that any student or postdoctoral researcher supported by NSF receive RCR training. NIH requires all individuals receiving training grants to undergo RCR training.

Responsible Conduct of Research (RCR) is defined as the practice of scientific investigation with integrity and involves the awareness and application of established norms and ethical principles in the performance of all activities related to scientific research. Montana State University expects that all research be conducted to the highest ethical standards by faculty, students, and staff. MSU's RCR training covers the core areas that are seen as significant in conducting research, including research misconduct, plagiarism, falsification, fabrication, data editing, authorship on manuscripts, conflict of interest, mentor-mentee relationships, and more. MSU training opportunities encourage critical thinking and engagement in discussions about what it means to be an ethical researcher.

Description	This training contains 9 required modules covering responsible conduct primarily with regard to: authorship, collaborative research, data management, mentoring, peer review, and plagiarism. An average score of 80% is needed to pass the training.
Completion Information	Upon completion of this training attendees will be authorized to work on a NSF funded research project.
Valid for	3 Years
Duration	About 2 Hours
Course Materials	No materials are required.
Training Outcome	At the conclusion of the training attendees will know: <ul style="list-style-type: none">• The basic concepts of RCR• RCR for most situations• Situations of research misconduct

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Research Misconduct

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](#)

Anonymous Reporting

[MSU Compliance Hotline](#)

ORC Director

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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	Training
All Animal Users and PIs	<ol style="list-style-type: none">1. CITI training.<ol style="list-style-type: none">a. Animal Biosafetyb. Investigators, Staff and Studentsc. Principal Investigators (if applicable)d. Species Specific Training2. Animal Care at MSU (face to face)<ol style="list-style-type: none">a. Introduction to Animal Care & Use at MSUb. Occupational Health and Safety3. Occupational Health and Safety Clearance<ol style="list-style-type: none">a. Completion of Risk Assessmentb. Medical History/Animal Allergy4. 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](#)

When might my university activities be subject to export and sanction regulations?

- I intend to host a foreign visitor at Montana State University
- I intend to travel outside of the United States.
- I intend to ship or carry items outside of the United States
- I intend to have foreign nationals participate in research activities
- I want to participate in an international collaboration
- I intend to accept restrictions on publication, foreign national participation, or involve proprietary information in my activity
- My activity will involve military, intelligence, space, encryption software, or nuclear related information, technical data, equipment, or software.

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](#)

Working With	CITI and Other Training
Surveys or research on Human Subjects (i.e. Student Projects)	Students and Class Projects
Social and Behavioral Research on Human Subjects	Social and Behavioral Research Investigators/Faculty
Biomedical Research on Human Subjects	Biomedical Research Investigators/Faculty
Data or Specimens Acquired from Human Subjects	Use of Data or Specimens Acquired from Human Subjects
Confidential Information	Use of Confidential Information, Privacy Security (IPS for Researchers)
HIPAA-compliant building and managing of online surveys and databases	REDCap Training
Clinical Trials	Clinical Trials and Good Clinical Practice

IRB Administrator

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Institutional Review Board
