Michigan State University

Essentials of Research Administration
Compliance
Tuesday, May 24, 2016 from 8:30 A.M. – 12:00 P.M.
The Henry Center

PROGRAM

8:30 A.M. – 8:40 A.M.  Introduction  Kristen Burt
8:40 A.M. – 9:00 A.M.  Institutional Animal Care and Use Committee  Sally Light
9:00 A.M. – 9:20 A.M.  Conflict of Interest  Brian Mattes
9:40 A.M. – 10:00 A.M.  Export Controls and Trade Sanctions  Rhett Butler
10:00 A.M. – 10:20 A.M.  Break
10:20 A.M. – 10:40 A.M.  MSU Technologies  Bradley Shaw
10:40 A.M. – 11:00 A.M.  Responsible Conduct of Research  Joseph R. Haywood
11:00 A.M. – 11:20 A.M.  Environmental Health and Safety  Kevin Eisenbeis
11:20 A.M. – 11:40 A.M.  Campus Animal Resources  Claire Hankenson
11:40 A.M. – 12:00 P.M.  Wrap-Up and Closing  Kristen Burt
MSU recognizes and embraces the fundamental interdependence of humans and animals and is committed to the core value of humane care and use of all animals.

Animal research is as carefully regulated as human research.

Most animal research is conducted primarily for the benefit of humans, not animals. But, unlike humans, animals cannot consent to participate in experiments or comment on their treatment, which creates special needs that should be taken into consideration in their care and use.
Who is Responsible for Animal Welfare?

System of Oversight

- Multi-tier accountability system
  - Federal - USDA, PHS, FDA, EPA
    - Unannounced annual visits by the USDA
  - Accreditation - AAALAC
  - Institutional Animal Care Program
  - Public: IACUC representation
Requirements for Animal Care Program

- Institutional Policies
- Appropriate husbandry
- Veterinary care
- Appropriate physical facilities

Components of an Animal Care Program

AV & Staff  
IACUC  
Investigator  
Administration

Each component must make its contribution so that the whole is greater than the sum of the parts.
Animal Care Program at MSU

- Campus Animal Resources
- Institutional Animal Care and Use Committee

Campus Animal Resources (CAR)

- Biomedical Facilities (formerly ULAR) - 12
- College of Veterinary Medicine Vivarium & Vet Research Farm
- University Farms (on and off campus)
  - On campus - 8 - Animal Science + Organic Farm
  - Off Campus - 4 - Michigan AgBioResearch
- Van Andel Research Institute, Grand Rapids

Attending Veterinarian oversees veterinary care in all of CAR.
IACUC

Institutional Animal Care and Use Committee

- The IACUC includes scientists, veterinarians, staff, and local community representation.
- Charged with oversight of all animals used in teaching and research at MSU.
- Develops institutional policies and guidelines.
- Ensures compliance within the program.

IACUC Responsibility

- Review animal use activities and significant changes
- Appropriate anesthesia, analgesia, and euthanasia
- Minimize pain and distress
- Search for alternatives to painful or distressful procedures
- Exercise for dogs; psychological well-being of primates
- Training of investigators and personnel
- Unnecessary duplication of experiments
- Semi-annual review of program and facilities; institutional report
- Review concerns about care and use of animals
- Suspend activities
IACUC Review Process

- Animal Use Form (AUF)
  [http://animalcare.msu.edu/iacuc-forms](http://animalcare.msu.edu/iacuc-forms)
- PI submits to IACUC office via email
- Internal Review
- Assigned to Committee members for review
- Review questions sent to PI
- Answers reviewed
- Verify training completed
- AUF approved or reviewed at monthly IACUC meeting

Timeline for Review

- AUFs submitted by email to [iacuc@msu.edu](mailto:iacuc@msu.edu)
- AUFs are sent out for IACUC review every Monday
- Allow 4-6 weeks for IACUC review.
- Once AUF approved, PIs notified and can order animals.
- AUFs are approved for 3 years.
- Records are retained for 3 years after inactivation.
Post Approval Monitoring

- Research Liaison
- Semiannual Inspections and Program Review

Summary

- Use of animals in teaching and research is regulated by law, Federal regulatory agencies, and MSU.
- IACUC oversees all use of animals in teaching, research, and testing.
- Animal work must be approved before use of animals is begun.
Contacts & Information

- IACUC Office
  - Phone: 432-4151
  - email: iacuc@msu.edu
  - Web: http://animalcare.msu.edu/IACUC

- Campus Animal resources (CAR)
  - Phone: 353-5064
  - Web: http://animalcare.msu.edu/car
Faculty/Academic Staff Conflict of Interest

Brian Mattes, Faculty Conflict of Interest Officer
  (mattesbr@msu.edu; 884-8045)
Brittany Bristol, Administrative Assistant
  (fcoio@msu.edu; 884-7000)
Marni Goodwin, Administrative Assistant
  (fcoio@msu.edu; 884-7000)

Conflict of Interest Disclosure and Training

http://coi.msu.edu/
In a Nutshell:

- **Who**: All faculty and academic staff appointed through the academic personnel system with research, teaching, outreach, or service responsibilities
- **What**: Must complete an Annual Disclosure of Significant Financial Interests
- **When**: Annually and within 30 days of acquiring a new interest
- **Where**: [http://coi.msu.edu/](http://coi.msu.edu/)
- **Why**: Requirement of MSU's Faculty/Academic Staff Conflict of Interest Policy, as approved by the Board of Trustees and Academic Governance
- **How**: [http://coi.msu.edu/how-to-disclose](http://coi.msu.edu/how-to-disclose)

What is a Financial Conflict of Interest?

- **Financial Conflict of Interest (FCOI)**: Situation where a person has a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research or other institutional responsibilities

- Faculty members must annually disclose all significant financial interests and **other opportunities for tangible personal benefit** that are related to the faculty member’s institutional responsibilities.
Why are we concerned about COI?
• We must maintain the trust of the general public which supports us and which we serve.
• We must promote objectivity in research and scholarship.
• An unmanaged conflict of interest can undermine confidence in the University and, thus, harm its standing and that of its entire faculty.
• An investigator’s interest could lead others to question their professional motives.
• Federal and state requirements mandate that financial conflict of interest policies and procedures be in place.

What is a significant financial interest (SFI)?
• Financial interests consisting of one or more of various types of financial interests that, when aggregated over the previous calendar year, exceeds $5,000, or…
• If the value is not evident (as with equity interest in a non-publicly traded entity, or travel that was paid on behalf of the investigator), then it must be considered an SFI.
  • Not only your own personal interests, but also financial interests held with or by your immediate family (spouse, domestic partner, dependent children, and other dependents) and with or by any legal entity that you or your family owns or controls.
Examples of Significant Financial Interests

- **Income** or payments of any kind totaling more than $5,000 over the last calendar year from a single entity;
- **Ownership** greater than 1% of a single outside entity or ownership interests greater than $5,000 (e.g., stock);
- **Intellectual property** rights or licenses with an established fair market value exceeding $5000 or which generate income of any value from other than MSU (including royalties from other domestic universities);
- **Unvalued options** for stock or ownership of any value in a private company;
- Serving on a governing or advisory board, or in a fiduciary or managerial role, or as a general partner with or without pay;
- PHS investigators must disclose travel paid for by entities outside the university (see exceptions on next slide)

Exceptions

- SFIs unrelated to your MSU Institutional Responsibilities;
- **MSU salary**, remuneration by MSU, or other payments at MSU's behest (including from an MSU-approved practice plan);
- SFIs from seminars, lectures, teaching engagements, or service on advisory committees or review panels paid by domestic (U.S.):
  - Federal, state, or local government agencies;
  - Institutions of higher education;
  - Academic teaching hospitals and medical centers; or
  - Research institutes affiliated with an institution of higher education.
  - (You do have to report nonprofits and foreign institutions)
Who manages COIs?

• The Conflict Review Committee (CRC)
  • Composed of at least five faculty members from different disciplines
  • Convenes ~ every 2 months

• The Conflict of Interest Office is managed by the Financial Conflict of Interest Officer (FCOIO)
  • Development of policies and procedures related to the identification and disclosure of significant financial interests,
  • Initial determination of potential conflicts of interest
  • Non-voting member of CRC

What happens if a COI is identified?

• The FCOIO, with the VPRGS and/or the CRC make a determination of appropriate action.

• Conflict Management Plan (CMP):
  • An agreement that sets out limits and restrictions on the investigator for the purpose of reducing or eliminating a conflict of interest, and to ensure that the design, conduct, and reporting of research will be free from bias.
  • May include:
    • public disclosure when presenting or publishing
    • Appointment of independent monitor
    • Meeting with chair and/or dean
    • Reduction or elimination of interest
    • Reporting to funding agency
MI Contracts of Public Servants with Public Entities Law

- Contract terms must be submitted to the Board of Trustees for review and approval when a contract is with:
  - an employee of the University;
  - any partnership or unincorporated association of which the employee is a partner, member, or employee;
  - any private corporation of which the employee is
    - a director, officer, or employee; or
    - a stockholder
  - any trust of which the employee is a beneficiary or trustee.

MI Contracts of Public Servants with Public Entities Law:

- Only the University President and specific authorized individuals may execute contracts on behalf of MSU.
- Conflicting interests created by the contract must be managed as a prerequisite for the Provost to recommend the contract terms to the Board for consideration.
- Law requires that the employee’s interest in a contract be disclosed to the Board of Trustees (BOT), and then the terms of the contract voted for approval at another meeting.
- Time must be allowed for review of possible conflict of interest, development and approval of a conflict management plan, and submission to the Office of General Counsel for inclusion on the Board agenda. [http://trustees.msu.edu/meetings/](http://trustees.msu.edu/meetings/).
MI Contracts of Public Servants with Public Entities Law

• Examples:
  • Purchase of goods or services
  • Licensing agreements involving intellectual property rights
  • Lease agreements for land or space use
  • Sponsored Projects funded by Small Businesses
  • Sponsored Project subcontracts to Small Businesses
  • Use of MSU facilities for private purposes

Need help?

Web: http://coi.msu.edu/

Email: fcoio@msu.edu

Phone: (517) 884-7000
Essentials of Research Administration: Human Research Protection Program

Kristen Burt
HRPP Director
May 24, 2016

MSU Human Research Protection Program

- Institutional Review Board Office
- Compliance Office
- Institutional Review Board Committees
Institutional Review Board Office

- Facilitates the MSU IRB review processes in accordance with federal, state, and local regulations, university policies, and ethical standards. Includes:
  - Pre-review of incoming applications to the IRBs
  - Coordinate the IRB review process
  - Review exempt applications and non-human subject determinations
  - Provide guidance regarding human subject protection requirements to researchers, IRB members, and other administrators

Compliance Office

- Conduct post approval monitoring to educate researchers and to ensure that research is conducted in accordance with federal, state, and local regulations, university policies, and ethical standards, and/or the requirements and determinations of the IRB
- Conduct a review of clinical research to provide oversight over regulatory areas that affect clinical research that are not addressed in the IRB requirements. Includes:
  - Health Insurance Portability and Accountability Act
  - FDA requirements for investigational new drugs and devices (21 CFR 312, 21 CFR 812)
  - Registration with clinicaltrials.gov (Public Law 110-85)
  - International Conference on Harmonisation Good Clinical Practice (E6)
  - Clinical research billing requirements
Institutional Review Board

- Review and approve research and/or clinical investigations involving human participants.
  - Comprised of individuals with varying backgrounds and expertise
  - Perform initial review of research
  - Includes continuing review responsibilities after approval
  - Focus on areas such as minimization of risk, assessment of risks and benefits, informed consent process, equitable recruitment and enrollment of subjects
- MSU IRBs
  - Biomedical and Health Institutional Review Board (BIRB)
  - Community Research Institutional Review Board (CRIRB) – Not For Much Longer, Though!
  - Social Science / Education / Behavioral Institutional Review Board (SIRB)

MSU IRB Requirement

- MSU IRB review and approval is required for all projects that involve research and/or clinical investigations with human subjects conducted by faculty, staff, students, or agents of MSU.
- A limited exception may apply if MSU has an arrangement to rely upon another IRBs review.
Why are the Definitions Important?

Research &/or Clinical Investigation + Human Subject = MSU IRB Review

Is an Activity Research?

“Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.” 45 CFR 46.102(d)

IMPORTANT:
1. At MSU, “research” includes the preparation of Masters Theses & Doctoral Dissertations
2. FDA “clinical investigations” involving “human subjects” also require IRB review
Does the Research Involve a Human Subject?

“Human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1) data through intervention or interaction with the individual, or
2) identifiable private information” 45 CFR 46.102(f)

Keep in Mind . . .

• MSU IRB approval must be obtained BEFORE any research begins

• Contact the MSU IRB if you have ANY questions of whether an activity requires MSU IRB review

• There are continuing review responsibilities
Hot Topics

• MSU
  • New Reliance Application to Rely Upon Another IRB
  • Clinical Research Billing Requirements

• Federal
  • Notice of Proposed Rulemaking for the Federal Policy for Protection of Human Subjects
  • Draft NIH Policy on the Use of a Single IRB for Multi-Site Research

MSU HRPP Resources

• Website: [www.hrpp.msu.edu](http://www.hrpp.msu.edu)
  • Contact Information
  • Consent Templates
  • Application Forms and Instructions
  • HRPP Manual

• Contact the HRPP with questions!
  • 517-355-2180
  • irb@msu.edu or hr@ora.msu.edu or CRBC@ora.msu.edu
Questions?
Export Control and Trade Sanctions: An Overview

Rhett L. Butler
Export Control and Trade Sanctions Analyst
butlerrh@msu.edu
May 24, 2016

Presentation Overview

- What is an export?
- What are export controls?
- What are trade sanctions?
- What is EAR? ITAR? OFAC?
- The MSU process – who, what, when, where and why?
What constitutes an export?

Any release of controlled technology, data, software or other item to a foreign national. Such release is deemed to be an export to the home country or countries of the foreign national, even if the person is currently residing in the United States. This rule does not apply to persons lawfully admitted for permanent residence in the United States.

(Hint: A restaurant conversation in the U.S. that transfers controlled information to a foreign national constitutes an export.)

What are export controls?

Export controls are federal laws that regulate the export of:

- technology and data relating to military applications listed on the U.S. Munitions List (ITAR) – enforcement agency - Department of State

  AND

- “dual use” technologies relating to items listed on the Commerce Control List (EAR) – enforcement agency – Department of Commerce
  http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear
What are trade sanctions?

- The Office of Foreign Assets Control ("OFAC") of the U.S. Dept. of the Treasury enforces economic and trade sanctions based on foreign policy, economic and national security goals. OFAC blocks interaction with terrorists, international narcotics traffickers and weapons violators, among others, as well as denying dealings with certain foreign entities.

(Partial list of sanctioned countries: Balkans, Burma, Cuba, Iran, North Korea, Sudan, Syria, Zimbabwe)

Why is it important to be aware of these laws?

Violations of EC&TS can result in personal & institutional liability & criminal penalties:

- **individual** and/or **institutional** fines and/or
- **individual** incarceration
- Shows due diligence by MSU regarding compliance
Applicability

These laws apply to all research activities whether or not there is a specific citation to the regulations in the grant or contract award document governing the project, and whether or not the project is grant funded.

These laws also apply to export-controlled information or technology shared with MSU by personnel outside the University (such as items or data shared via a material transfer or confidential disclosure agreement).

Licenses?

- In certain situations, the University may elect to apply for a license for export but:
  - They take time (months)
  - They can be expensive
  - They can be turned down
Fundamental Research

Fundamental research is basic or applied research at an accredited institution of higher learning in the U.S. where the resulting information is not restricted in the form or content of its release to the public and is ordinarily published and shared broadly in the scientific community.

Publication & Fundamental Research

The fundamental research exclusion does not in general extend to the for-profit sector (export controls sometimes flow down to a university as a subcontractor when the for profit, as prime contractor, is required to accept the controls).

The fundamental research exclusion does not extend to research performed outside the University even if the research is fundamental at MSU.
From Section VI of the MSU Faculty Handbook:

The University should retain for its scholars the right of first publication. The imposition of restriction on publication of research results is incompatible with the basic concept of an educational institution. Exigencies of national defense may at times make exceptions to this policy on publication necessary.

- The University Research Organization
  - allows MSU to conduct research projects that we otherwise could not take due to control status or contractual publication restrictions or restrictions on the involvement of foreign nationals.
So … What does it all mean?

The Export Control and Open Research Review Worksheet (ECORRW) helps EC&TS determine whether or not a project is controlled, what publication or citizenship restrictions apply, and what follow-up actions must be taken to comply with U.S. law and regulation and MSU policy.


Export Control Worksheet

- May be found at: http://forms.exportcontrols.msu.edu
- May be filled out at proposal stage or at the award stage after an e-transmittal has been fully routed.
- Non-FRE projects are sometimes pursued via contract training or testing agreements (students’ rights must be protected). An Access Control Plan may be required OR the project may be referred to the URO (PI, dept. and college must agree).
- PI signs, dean/associate dean/chair signs (unit preference), forward to Office of Sponsored Programs.
- OSP signs on contract terms, forwards to ECTS for review and signature.
What is an access control plan?

- Protects controlled technology/data for projects not under FRE.
- May require keeping equipment, computers and/or data in secure areas, other security measures as needed to restrict access.
- ACPs are prepared by ECTS and reviewed periodically.

Some other thoughts

- Be careful about faculty and staff travelling overseas with laptops (a “clean” laptop is best).
- Federal regulations require sign-off for EC considerations on visa applications (visit http://forms.exportcontrols.msu.edu to access the online form).
- MSU has a site license to “Visual Compliance” - searchable listings of items on the ITAR and EAR lists and restricted parties (please contact ECTS for an ID).
- MSU has a site license to online export control training through CITI (access information may be found at http://exportcontrols.msu.edu/training).
Contact Export Control and Trade Sanctions at:

- Phone: (517) 432-4499
- Email: export@msu.edu
- Website: http://exportcontrols.msu.edu
- Address: 249 Administration Building

Thank You!
Intellectual Property in Research Administration

Brad Shaw
Technology Manager
MSU Technologies

What Does Success Look Like?

Great Idea
Great Results
Great Patent
Great Publication
Great Product
Public Benefit

carboplatin

Technology Transfer
Commercialization

Tamiflu 75 mg
Hematopoeisis Stimulation
75 mg
Zum Krankheiten
10 Kapseln
What is intellectual property (IP)?

Intellectual property (IP) protection provides the owner with a right to exclude others from doing something (limited monopoly).

- **Patent** - Protects new and useful compositions, machines, articles of manufacture, or processes;
- **Copyright** - Protects literary, musical and dramatic works, pictorial, sculptural and audiovisual works, and other kinds of works of authorship, including computer program expression;
- **Trademark** - Protects a word, a group of words, or a logo that is used in connection with the sale of goods to distinguish them from those made or sold by others.

**Bayh-Dole Act**

- U.S. legislation enacted by Congress (Dec. 12, 1980) dealing with IP from federal government funded research;
- Transfers title to inventions made using U.S. government grants from government to academic institution;
- Reporting requirements to disclose invention to the funding agency;
- Grant federal government a non-exclusive, non-transferable, paid-up license to practice worldwide;
- Actively promotes commercialization;
- Share royalties with inventor;
- Preference to U.S. industry and small business.
MSU Patent Policy

MSU claims ownership of all discoveries or inventions:

- By any employee of MSU using University funds or funds administered by MSU;
- Results from employees’ duties with the University;
- Has been developed in whole or in part through use of MSU facilities and resources.

Thus MSU owns most intellectual property resulting from research conducted at MSU.

Patent Policy

<table>
<thead>
<tr>
<th>Net Licensing Proceeds on a Particular University Invention</th>
<th>Inventor(s)</th>
<th>Major Administrative Unit</th>
<th>University</th>
</tr>
</thead>
<tbody>
<tr>
<td>First $5,000</td>
<td>100%</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Next $100,000</td>
<td>33 1/3%</td>
<td>33 1/3%</td>
<td>33 1/3%</td>
</tr>
<tr>
<td>Next $400,000</td>
<td>30%</td>
<td>30%</td>
<td>40%</td>
</tr>
<tr>
<td>Next $500,000</td>
<td>20%</td>
<td>20%</td>
<td>60%</td>
</tr>
<tr>
<td>All Additional Net Licensing Proceeds over $1,005,000</td>
<td>15%</td>
<td>15%</td>
<td>70%</td>
</tr>
</tbody>
</table>
Typical IP Documents

- Invention Disclosures (ID);
- Sponsored Research Agreements (SRA)*;
- Confidential Disclosure Agreements (CDA or NDA);
- Material Transfer Agreements (MTA);
- Option Agreements;
- License Agreements;
- Interinstitutional Agreements (IIA);
- Small Business Innovative Research Program (SBIR) & Small Business Technology Transfer (STTR) Program – Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization.*

*Consult MSUT as needed.

Language to watch out for

- Granting any commercial rights
  - “an irrevocable, non-exclusive, royalty-free, worldwide license”
  - “work made for hire”;
- Claiming ownership of data, research results;
- Language which prescribes royalty distributions from any licensed technology;
- Prescribing any specific licensing terms;
- Grants covering the same scope as earlier awards;
- Granting rights other than internal research rights to any background of future IP (improvements).
Yours, Mine, and Ours

Scope of Work

Sponsor Innovations
Joint Innovations
University’s Innovations

Background IP | Project IP | Future IP

1  | 2  | 3
4  | 5  | 6
7  | 8  | 9
10 | 11 | 12

Time
Yours, Mine, and Ours

- Sponsor Innovations
- Joint Innovations
- University Innovations

Background IP | Project IP | Future IP | Scope of Work
---|---|---|---
1 | 4 | 9 | 5
2 | 2 | 10 | 6
3 | 3 | 11 | 7
4 | 6 | time | 8
5 | 9 | 11 | 10

Available for license

3rd Party Overreach
The Freedom of Information Act ("FOIA")

Selected FOIA Exemptions

- A trade secret or privileged or confidential commercial or financial information obtained from a person;
- Original works of authorship created by a person employed by or under contract to the University until a reasonable opportunity is provided for the author to secure copyright registration;
- Records regarding a patentable invention until a reasonable opportunity is provided for the inventor to secure patent protection;
- Trade secrets or other proprietary information that is determined to have potential commercial value, if a general description of the nature of the information and the University's interest is made available upon request.

When to contact MSUT?

- Whenever you need clarification on MSU IP policy;
- Every attempt should be made to negotiate first with other party. If it cannot be resolved, then please contact Rich Chylla or Anne DiSante at MSUT;
- If the PI indicates there is background IP, we want to know about any grants of rights to both background and foreground IP.
What do we want to know?

- A statement of work;
- A copy of the proposal/contract/document in question;
- The issues/language which needs resolution should be spelled out clearly in the email;
- Ask the PI these questions and include in email response:
  - What is the likelihood that IP will be created or developed from this project?
  - Does this relate to anything you or others on the project created/developed in the past? Anyone on the project bringing creations from other funded projects needs to alert us to the past creations which may be restricted in use.
    - What are the deliverables for this project?
    - If software or database, does the researcher want to just give this to anyone?
    - Are there other sources of funding for this project?

Questions?

Contact us...

MSU Technologies
325 E. Grand River, Suite 350
East Lansing, MI 48823
Phone: 517-355-2186
E-mail: shawbr@msu.edu

www.technologies.msu.edu
Responsible Conduct of Research

Essentials of Research Administration Compliance

J.R. Haywood
Assistant Vice President for Regulatory Affairs
Office of Regulatory Affairs

"responsible conduct of research is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research."

National Institutes of Health

Misconduct: Research Misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results

Plans Developed and Implemented

- Basis: America Competes Act making it a requirement for all NSF grants
- Development of Institutional Policy
- Expansion to other agencies – NIH and USDA (NIFA awards)
- Rigor and Reproducibility requirement is imminent

Requirement

Responsibility for academic content generally resides with the faculty of each academic unit, subject to review and approval through established academic governance procedures. We know and expect that all MSU units already address aspects of responsible and ethical conduct of research and scholarly/scientific activities in their existing curricula. All respected undergraduate and graduate programs do. The quality of our research and scholarly activities depends on it.

We want to stress that we believe adherence to academic norms, professional standards, and legal requirements for the responsible conduct of research, as well as to the principles on which those norms, standards, and requirements are based, should be an expectation and not just a goal. Thank you for your time and deliberations in this process.
Michigan State University Policy

**INSTITUTIONAL POLICY FOR TRAINING AND OVERSIGHT IN THE RESPONSIBLE AND ETHICAL CONDUCT OF RESEARCH**

Each student and postdoctoral researcher appointed as an hourly employee, graduate assistant, postdoctoral fellow, research associate, or visiting researcher who contributes to the design, conduct, or reporting of an NSF-funded project shall be trained in the responsible conduct of research, research integrity, and ethical responsibilities associated with the conduct of that research project. A minimum of five hours of formal training is required for each such student and postdoctoral researcher. Training shall be updated annually (minimum of three hours) throughout the student’s or postdoctoral researcher’s appointment on the NSF-funded project.

Graduate School. Plans must be approved by the collegiate dean responsible for the department, school, and/or graduate program prior to submission to the Graduate School. The Dean of the Graduate School will provide to the Office of

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**Who needs to take RCR training?**

- **Doctoral Graduate Students**
  - Graduate School requirement; some programs/colleges may require training for Masters and Professional Masters programs
- **NSF Grants**
  - “Undergraduate students, graduate students and postdoctoral researchers participating in the proposed research”
- **NIFA Grants**
  - “Program Directors, faculty, undergraduates, graduate students, postdoctoral fellows and some staff”
- **NIH Grants**
  - “Trainees, fellows, participants and scholars” on training, career development, education and dissertation research grants
Moving Forward

- Graduate students will need to satisfy both online and face-to-face training requirements
- Others presently only need to satisfy online requirements
- Completion will be tracked by the Office of Regulatory Affairs and semiannual updates will be provided to the departments
Environmental Health and Safety Programs

Kevin Eisenbeis, Director
Environmental Health and Safety (EHS)

The Mission of Environmental Health and Safety

Environmental Health and Safety (EHS) supports the mission and guiding principles of Michigan State University through leadership, guidance, education and partnership to promote and establish programs in health and safety, protection of the environment and regulatory compliance.
Environmental Health and Safety Overview:
Protecting People and Managing Risk

- EHS is the office with primary responsibility for the management and oversight of both research-related and operationally-related environmental health and safety programs and compliance.
- EHS is also charged with the oversight and management of the University’s technical environmental responsibilities, including the management of all major environmental permits and licenses.
- EHS develops and provides occupational health and safety training to over 11,000 employees and students each year. Major areas of responsibility include:
  - Radiation Safety
  - Chemical Hygiene
  - Biosafety
  - Industrial and Occupational Safety
  - Environmental Management and Compliance

Radiation Safety

The Radiation Safety Staff oversees the use of radioactive materials on campus and serves as an information resource for the laboratory personnel. The following is a list of services offered by the Radiation Safety Staff.

- Training
- Surveys and inspections
- Radioactive materials approvals
- Order, receipt, inventory, monitoring, transfer, & delivery of radioactive shipments on campus
- Shipment of radioactive materials off campus
- Radiation exposure monitoring - dosimetry and bioassays
- Contamination monitoring
- Environmental radiation monitoring
- Shielding assessments
- Calibration of radiation equipment
- Exposure assessment and tracking
- Incident and spill response
- Leak testing of sealed sources
Chemical Safety

The Chemical Safety Staff oversees the University’s teaching, research, outreach and support activities involving the use, storage, transportation and disposal of hazardous chemicals. The following is a list of services offered by the Chemical Safety Staff.

- Training
- SDS searches
- Chemical safety laboratory inspections
- Chemical fume hood testing
- Industrial hygiene consultations
- Indoor air monitoring
- Research review
- Occupational injury reports
- Spill response

Biological Safety

The Biological Safety Staff is here to provide laboratory personnel with the knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. The following is a list of services offered by the Biological Safety Staff.

- Training
- Biological safety laboratory and clinical inspections
- Autoclave inspections
- Assistance with transportation of infectious substances
- Scheduling of biological safety cabinet and laminar flow hood certifications
- N-95 Respirator fit-testing / training
- Follow-up to biologically related occupational injuries
- Biological safety consultation for animal use
- Biological spill response
Industrial and Occupational Safety

The Occupational Safety Staff provides University wide training, operator evaluation, inspections, procedure development and written plans for a comprehensive set of occupational safety programs. The following is a list of services offered by the Occupational Safety Staff.

- Training
- SDS searches
- Industrial hygiene consultations
- Indoor air monitoring
- Occupational injury reports
- Respirator training/fit-tests
- PIT/Forktruck training/permits
- Aerial lift training
- Shop inspections
- Lock out/tag out procedures

Environmental Management and Compliance

The Environmental Safety Staff is responsible for the management and oversight of research-related environmental health and safety programs. The following is a list of services offered by the Environmental Safety Staff.

- Asbestos
- Lead
- Universal waste (fluorescent tubes, batteries, light ballasts, mercury-containing devices)
- Stormwater management
- Emergency Management System (EMS)
- Spill Prevention, Control and Countermeasure (SPCC)
- Pollution Incident Prevention Plan (PIPP)
- Toxic Substances Control Act (TSCA)
- Resource Conservation and Recovery Act (RCRA)
- Clean Air Act (CAA) Titles V and VI
General Training Information

The EHS provides live and on-line training classes throughout the year to educate the employees and students of Michigan State University on safe work practices. Completion of these courses by MSU personnel ensures that the university is fulfilling local, state and federal requirements in radiation, chemical, biological, hazardous waste, and environmental safety.
Training Programs Provided by EHS

Training programs provided by EHS include:

- Aerial Lift
- Analytical X-Ray Radiation
- Asbestos Awareness
- Biological Safety
- Biological Substance Shipping
- Biosafety Principles
- Bloodborne Pathogens
- Chemical Hygiene and Laboratory Safety
- Compressed Gas Cylinder Safety
- Confined Space
- Cranes
- EPA-Lead Management
- Hand Tools
- Hazard Communication
- Hazardous Waste
- Hearing Conservation
- Lifting and Back Safety
- Lock Out/Tag Out
- Medical Waste
- Monkey B
- Personal Protective Equipment
- Powered Industrial Trucks (Forktruck)
- Radiation Safety
- Radiation Sealed Source
- Respirator
- Respirator (N-95)
- Right To Know
- Scaffolding and Ladders
- Security Awareness
- Soil Moisture Gauge
- SPCC/PIP Management
- Storage Tank Management
- Title VI CFC Management
- Tractors
- TSCA Overview
- Universal/RCRA Regulation Overview
- Well-Head Protection Program

MSU Is A Highly Regulated Entity

- Michigan Department of Natural Resources & Environment (MDNRE)
  - Licensed power plant and related infrastructure
  - Licensed pathological waste incinerators
  - Licensed Concentrated Animal Feeding Operation (CAFO)
  - Licensed Storm-water System
- US Environmental Protection Agency (EPA)
  - Licensed TSD hazardous waste facility
  - Licensed Spill Control and Countermeasure Plan
- Nuclear Regulatory Commission (NRC)
  - Licensed low level radiation waste storage facility
  - licensed radioactive waste incinerator
  - licensed Cyclotron (NSCL)
- Food & Drug Administration (FDA)
  - Licensed radio-pharmacy (Radiology)
- Centers For Disease Control (CDC)
  - Licensed Biohazard Level 3 research facility (DCPAH)
  - Licensed Select Agent Laboratories
- Michigan Occupation Safety and Health Administration (MIOSHA)
How to Contact EHS?

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