Essentials of Research Administration: Introduction to Compliance

Kristen Burt
Office of Regulatory Affairs
March 10, 2015
What This Course Will Cover

• Office of Regulatory Affairs
• Environmental Health and Safety
• Animal Care Program
• Human Research Protection
• Export Controls and Trade Sanctions
• Conflict of Interest
Objectives of This Course

• Introduce you to individuals associated with various compliance programs

• Provide a high level overview of many compliance areas

• Provide resources and information about who to contact with questions
Important Considerations

• It is important to be aware that:
  • review and approval from one or more units may be required before initiation of the activity
  • training and tracking of training may be required
  • requirements may apply regardless of funding source

• Check with the appropriate unit for review, approval, training, and other requirements or if you have any questions
Why Do I Need to Know This if I’m Not Involved in These Areas?

- You never know what the future holds!
- Provides you with the ability to identify and spot potential issues
- Know who or what offices to contact with questions
Essentials of Research Administration: Office of Regulatory Affairs

Kristen Burt
Office of Regulatory Affairs
March 10, 2015
Topics

- Who are we?
- What do we do?
- Recent challenges?
- Recent projects?
- How can we help you?
- How do you find us?
Who We Are?

• Animal Care Program
• Environmental Health and Safety
• Human Research Protection Program
• Institutional Stem Cell Research Committee

• Reports to the Vice President for Research and Graduate Studies
What We Do?

• Facilitate research
• Maintain compliance with state and federal laws, regulations and policies
• Training
• Accreditation
• Protect the research subject and the investigator
Recent Challenges?

• High activity in proposed and final rulemaking
  • Oversight of animals
  • Select agents
  • Human research protection
  • Conflict of interest

• Intention to reduce regulatory burden
Recent Projects?

• Implementation of the Saba Learning Management System (LMS)
  • Centrally administer registrations, reminders, and tracking of course completion
  • Includes EHS, HRPP, and ACP training records

• AAHRPP and AAALAC accreditation processes
How can we help you?

• Assist in working through protocol approval process
• Help stay in compliance through post-approval monitoring
• Work with faculty, staff, and students to ensure a safe work environment
How do you find us?

- Office of Regulatory Affairs
  - Website: [http://www.ora.msu.edu/](http://www.ora.msu.edu/)
  - Phone: 517-432-4500
  - Email: ora@msu.edu
  - 204 Olds Hall
The Office of Regulatory Affairs' (ORA) mission is to:

- promote the responsible conduct of research,
- assure compliance with federal, state, and university regulations and policies on research,
- serve as a campus resource for research ethics education materials and training,
- protect the rights and welfare of research subjects,
- protect public health and safety,
- assure the objectivity and integrity of research.

"Protection of a research environment for free and unfettered pursuit of knowledge is an important University responsibility. Infringement on this freedom must be restricted to those factors which are clearly essential to the protection of individuals and the public at large." - from the Michigan State University Faculty Handbook

Announcements
MSU's Authorship Guidelines Updated
MSU's Research Integrity Committee has released new general guidelines on authorship and creative works for public distribution. However, most journals or websites for publications state criteria for authorship, and the journal/group to which one intends to submit work should take... more
Questions?
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
- MSDS 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
- MSDS 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.
EHS TRAINING PROGRAM TRACKING

Number of Trained Faculty, Staff and Student Employees and Number of Training Courses Completed

Courses
Workers

Year
<table>
<thead>
<tr>
<th>Training Programs Provided by EHS</th>
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<td>Training programs provided by EHS include:</td>
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<tr>
<td>• Aerial Lift</td>
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<tr>
<td>• Analytical X-Ray Radiation</td>
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<tr>
<td>• Asbestos Awareness</td>
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<tr>
<td>• Biological Safety</td>
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<tr>
<td>• Biological Substance Shipping</td>
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<tr>
<td>• Biosafety Principles</td>
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<tr>
<td>• Bloodborne Pathogens</td>
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<tr>
<td>• Chemical Hygiene and Laboratory Safety</td>
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<td>• Compressed Gas Cylinder Safety</td>
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<td>• Confined Space</td>
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<tr>
<td>• Cranes</td>
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<td>• EPA-Lead Management</td>
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<tr>
<td>• Hand Tools</td>
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<td>• Hazard Communication</td>
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<td>• Hazardous Waste</td>
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<td>• Hearing Conservation</td>
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<td>• Lifting and Back Safety</td>
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<td>• Lock Out/Tag Out</td>
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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)
When Should you to Contact EHS?

Main Office Number: 355-0153
Web: EHS.msu.edu
E-Mail: EHS@msu.edu
Kevin Eisenbeis
Director, EHS
432-5275
eisenb14@msu.edu
ehls.msu.edu
Animal Care Program & Institutional Animal Care and Use Committee (IACUC)

http://animalcare.msu.edu

Sally Light
IACUC Administrator
421 West Fee Hall
517.353.9705
lights@msu.edu
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.
University policy specifies that:

- all animals under University care (that is, involved in projects under the aegis or sponsorship of the University) will be treated humanely;
- prior to their inception, all animal projects receive approval by the Institutional Animal Care and Use Committee (IACUC);
- MSU will comply with state and federal regulations regarding animal use and care.

Faculty members planning to use live vertebrate animals for any University-related activity must submit an animal use form (AUF) to the IACUC for review, or request an exemption from the Committee Chairperson and receive approval, prior to the start of the project, regardless of the source of funding for the project.
Who is Responsible for Animal Welfare?
System of Oversight

- Multiple federal and private agencies
- State & local laws and regulations
- Multi-tier accountability system
  - Federal – USDA, PHS, FDA, EPA
  - 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

Each component must make its contribution so that the whole is greater than the sum of the parts.
IACUC

Institutional Animal Care and Use Committee

Charged with oversight of all animals used in teaching and research at MSU.
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) [www.iacuc.msu.edu/forms](http://www.iacuc.msu.edu/forms)
- PI submits to IACUC office via email
- Internal Review
- Assigned to Committee members
- 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
- 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.
Campus Animal Resources (CAR)

- Biomedical Facilities (formerly ULAR) – 8
- 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

Attending Veterinarian oversees veterinary care in all three areas of CAR.
Animal Ordering

All animals coming into ULAR or Vivarium Facilities MUST be ordered through ULAR. Farm animals on campus are ordered through the Animal Science Department.
Campus Animal Resources Laboratory Ordering System. http://www.ular.msu.edu/CARLOS.html

- PIs order animals online
  - Approved AUF
  - Available amount of animals for order on AUF
  - Valid MSU account number
- Linked into AUF for approved animal numbers
- Account numbers entered by department Fiscal Officers

Animals are ordered from vendors weekly on Wednesdays, delivered following week. http://www.animalresources.msu.edu/order_process.html

Budget Responsibility for Animal Orders

- It is the responsibility of each department to request only such materials, services, or animals as can be paid out of available funds.

IMPORTANT! Especially for NIH/PHS funding - Funds may ONLY be used for activities specified in the grant.

Notice Number: NOT-OD-10-081  April 15, 2010

Summary

- Use of animals in teaching and research is regulated by law, Federal regulatory agencies, and MSU.
- IACUC oversees all use of animal in teaching, research, and testing.
- Animal work must be approved before use of animals is begun.
- Departments are responsible for making sure animals ordered, per diems, and supplies are charged to the appropriate account number.
Contacts & Information

- **IACUC Office**
  - Phone: 432-4151
  - email: iacuc@msu.edu
  - Web: [http://animalcare.msu.edu/IACUC](http://animalcare.msu.edu/IACUC)

- **CAR**
  - Phone: 353-5064
  - Web: [http://animalcare.msu.edu/car](http://animalcare.msu.edu/car)
Essentials of Research Administration: Human Research Protection Program

Kristen Burt
Interim HRPP Director
March 10, 2015
MSU Human Research Protection Program

- Institutional Review Board Office
- Human Research Liaison Office
- Clinical Research Billing 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
  - Provide guidance regarding human subject protection requirements to researchers, IRB members, and other administrators.
Human Research Liaison 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 Compliance Office

- Provide resources to the research community and others involved in patient care activities during research studies to ensure proper billing of health care services and items according to federal, state, and local regulations. Includes:
  - Conduct the required prospective Medicare Coverage Analysis (MCA) in accordance with the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination 310.1
  - Develop detailed study budgets for clinical research studies generating billable events
  - Identify applicable CPT/HCPCS codes for billable events for the clinical team to review
  - Negotiate budgets directly with Sponsors and/or Clinical Research Organizations
  - Review informed consent cost language to ensure consistency with other study documents
  - Review and negotiate payment terms in contracts/agreements (as applicable)
  - Obtain local Medicare Administrative Contractors approval for Investigational Device Exemption Studies (as applicable)
Institutional Review Board

- Review and approve research 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)
  - Social Science / Education / Behavioral Institutional Review Board (SIRB)
MSU IRB Requirement

• MSU IRB review and approval is required for all projects that involve research 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 + 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
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](mailto:irb@msu.edu) or [hrl@ora.msu.edu](mailto:hrl@ora.msu.edu) or [CRBC@ora.msu.edu](mailto:CRBC@ora.msu.edu)
Questions?
Export Control and Trade Sanctions: An Overview

Loraine J. Hudson
Director of Research Facilitation and Dissemination
March 10, 2015
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
  
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 Projects.
- 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!
(Questions?)
Faculty/Academic Staff Conflict of Interest

Brian Mattes, Faculty Conflict of Interest Officer  
(mattesbr@msu.edu; 884-8045)  
Brittany Bristol, Administrative Assistant  
(fcoiio@msu.edu; 884-7000)  
Melanie Westlund, Administrative Assistant  
(fcoiio@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: fcoiio@msu.edu

Phone: (517) 884-7000
CASE STUDY