Responsible Conduct of Research Workshop Series, 2015-2016

Conflict of Interest, Peer Review & Export Control

-- January 13, 2016--
Expectations

- Read the Syllabus for each Workshop
  - Pre-Workshop Readings and completing the Pre-Workshop Tasks are important for identifying the issues and questions that are most important to your interests.

- Because these sessions are designed to promote discussions, **no cell phones or laptops will be allowed on desks or be used during the workshops.**
Obligations of Researchers / Scholars

- “… researchers have an obligation to honor the trust that their colleagues place in them.”
- “… researchers have an obligation to themselves.”
- “… researchers have an obligation to act in ways that serve the public.”

Three Areas of Emphasis

- Conflicts of Interest
- Peer Review/Bias
- Export Control
Pre-Workshop Tasks

- **Discuss** with your research integrity consultant an event in your world that may be perceived as a conflict of interest, and how you would manage this.
Conflict of Interest
Objectives

- Define “financial conflict of interest” and give actual or hypothetical examples from your discipline
- Define “conflict of commitment” and give actual or hypothetical examples from your discipline
- Indicate why financial conflicts of interest are not inherently bad
- Describe ways in which conflicts of interest may affect trust in research results, the researcher's reputation, and the university reputation
- Understand ways of disclosing, managing, reducing, or eliminating financial conflicts of interest
Objectives, continued

- Understand the major provisions of MSU's Conflict of Interest Policy
- Identify the office or offices at MSU that handle concerns about conflict of interest
What is Conflict of Interest?

- **Conflict of Interest (COI):** Situation where a person is trusted to act impartially to make unbiased professional decisions, yet the person has personal interests that could influence or "bias" professional judgments and actions;

- Situation where one’s actions and motives may be questioned because of competing interests.

Source: Conflict of Interest – Michigan State University, http://coi.msu.edu/definitions

“... conflicts of interest can create an impression of impropriety that, in the long run, might undermine the credibility of an individual or even an entire profession. At a time when policymakers, politicians and the public increasingly rely on scientific advice about controversial issues—for example, human embryonic stem cells, genetically modified crops or global climate change—conflicts of interest diminish the public's trust in the independence and unbiased judgement [sic] of academic scientists. To maintain trust, researchers must remain visibly trustworthy, which requires a careful and explicit management of conflicts of interest.”

“Universities involved in federally sponsored medical research rarely take steps to investigate, reduce, or eliminate financial conflicts of interest among their scientists, a government audit report said Thursday.

“The report, by the inspector general of the Department of Health and Human Services, is the latest in a series of audits over the years that have criticized both universities and the National Institutes of Health, which distributes $24-billion a year in research money, as insufficiently attentive to biases affecting the reliability of American medical research.”

URL: http://chronicle.com/article/Federal-Audit-Faults/49220/
Why Do Conflicts of Interest Matter?

- In medical research, education, and practice
  - “... conflicts of interest threaten the integrity of scientific investigations, the objectivity of professional education, the quality of patient care, and the public’s trust in medicine.”

- Similar concerns exist in other scientific disciplines
Why Do Conflicts of Interest Matter, continued

- **Scientific integrity**
  - Conflicts of interest may (but not always) lead to bias that can affect the outcomes of research
  - The scientific record may be distorted
  - People who base decisions on research results may make unwise decisions if those results are inaccurate

- **Objectivity in education**
  - Faculty/mentor conflicts of interest may lead to presentation of biased information or research approaches to students/trainees
Why Do Conflicts of Interest Matter, continued

- Preserve public trust
  - Faculty members hold positions of trust within the university, scholarly community, and public
  - Unmanaged conflicts of interest erode trust and may contribute to:
    - A lower likelihood that research results will be believed and used
    - Damaged relationships with colleagues
    - Damaged reputations for the investigator and possibly the institution and other researchers
    - Less probability of receiving financial support for research in the future
Financial Conflicts of Interest

Financial conflicts of interest “are situations that create perceived or actual tensions between personal financial gain and adherence to the fundamental values of honesty, accuracy, efficiency, and objectivity.”

*ORI Introduction to the Responsible Conduct of Research,*
http://ori.dhhs.gov/education/products/RCRintro/
According to federal regulations, **financial conflicts of interest** may include:

- Salary or other payments for services, such as consulting fees or honoraria
- Equity interests, such as stocks, stock options, or other ownership interests
- Intellectual property rights, such as patents, copyrights, and royalties from such rights

National Institutes of Health

MSU start ups...some examples

- Biophotonic Solutions Inc.
- LifeBlood
- NamesforLife
- Phenometrics
A conflict of interest exists “when a faculty member’s financial interests or other opportunities for tangible personal benefit may compromise or reasonably appear to compromise, the independence of judgment with which the faculty member performs his/her responsibilities at the University.”
Financial Conflicts:

MSU Financial Conflict of Interest Policy
http://coi.msu.edu/

- **Disclosure** – a faculty or staff member must disclose a conflict of interest to her/his unit administrator as soon as she/he is aware of the conflict.

- **Significant financial interest** A financial interest consisting of one or more of various types of financial interests that, when aggregated over the previous calendar year, exceeds $5,000.

- **Review, management, and resolution of reported conflicts of interest** – the unit administrator must take a leadership role.

- **Michigan Contracts of Public Servants with Public Entities Law** – Board of Trustees approval is required when the financial interest involves an entity owned partly or managed by an MSU employee.
Example: Conflict-of-Interest Concerns Halt NIH Project at Emory U. (10/15/08)

“The National Institutes of Health has stopped a major $9.3-million, five-year study at Emory University because of concerns over payments made by drug companies to the former chief researcher on the project. The university received funds for the first two years of the project, a study on depression, but the NIH froze the rest of the money for the study …” The article further explains that the PI for the project failed to disclose nearly $2M received from pharmaceutical companies between 2000 and 2007.

Example: Nature Publishing Group’s Policy for Authors on Competing Financial Interests

“In the interests of transparency and to help readers to form their own judgements of potential bias, Nature journals require the authors of most articles to declare at the end of the manuscript any competing financial interests in relation to the work described.” … (policy continues)

Nature Publishing Group, For Authors and Referees
http://www.nature.com/authors/editorial_policies/competing.html
Key Student / Postdoctoral Trainee Interests

☐ Will a student’s or post-doctoral trainee’s efforts contribute to the completion of work related to the conflict of interest situation?
  ☐ Will the student’s work contribute to their thesis / dissertation or other project for academic credit?
  ☐ Are there any constraints or restrictions imposed on reporting or publication by graduate students or postdoctoral trainees as a result of their efforts related to the conflict of interest situation?

☐ Does the faculty member plan to serve as graduate committee chair or member of the graduate committee for these graduate students or supervise a post-doctoral trainee?
Managing Financial Conflicts

- Focus on maintaining the trust by others that academic and scientific decisions are made responsibly
  - “You do not have to do anything improper to have a conflict of interest; it is strictly situational.” Friedman, Paul J. (1992). The Troublesome Semantics of Conflict of Interest. Ethics & Behavior, 2(4), 245-251.

- Presence of conflict of interest does not mean that there has been or will be a misdeed

- Failure to disclose a conflict of interest is a misdeed
Managing Financial Conflicts: Disclosures

- Multiple disclosures to the institution
  - To Faculty Conflict of Interest Committee
  - To Grants and Contracts
  - To IRB and Data Safety Monitoring Committees
  - To Participants
- Disclosures in publications
- Disclosures in presentations
- Disclosures on web sites
- Disclosures to advisory groups/study sections
- Disclosures to companies, foundations, and associations
- Disclosures to regulatory agencies (e.g., FDA)
Managing Financial Conflicts:
Conflicts that Require Reporting

- Any financial or other interest that may affect the way a faculty member performs his/her duties at the University
- Any financial interest that might cause an independent observer to reasonably question whether the faculty member’s professional actions or decisions are affected or determined by considerations of personal gain arising from that financial interest
Managing Financial Conflicts:
Management and Resolution

- Disclose – tell someone who can provide advice and supervision, or who has a need to know
- Manage – ask objective reviewers to monitor activities, separate responsibilities for financial and research decisions, modify the research plan, appoint another faculty member to supervise trainees
- Reduce – make conflicts less severe or troublesome using any of the methods on this slide
- Eliminate – decide not to do the research or disqualify a researcher who has a serious conflict of interest
All faculty must Annually Disclose
Questions about Conflict of Interest

- MSU Faculty Conflict of Interest Policy
  [http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm](http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm)

- MSU Faculty Conflict of Interest Handbook
  [https://www.msu.edu/~biomed/COI/COIHandbook.html](https://www.msu.edu/~biomed/COI/COIHandbook.html)

- MSU Conflict of Interest Information Officer
  Brian Mattes
  105D Olds Hall
  Phone 517-884-7000
  Email fcoio@msu.edu
Sources

- **MSU Faculty Conflict of Interest Policy**
  [http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm](http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm)

- **MSU Faculty Conflict of Interest Website**
  [http://coi.msu.edu/](http://coi.msu.edu/)
JUDGING QUALITY RESEARCH / SHOLARSHIP

Insuring Fairness & Objectivity in PEER REVIEW!
Peer Review

- “Peer review (also known as refereeing) is the process of subjecting an author's scholarly work, research, or ideas to the scrutiny of others who are experts in the same field.”

- Helps to establish the quality of the research and manuscript – it is judged by experts

- Contributes to fair editorial decisions about what does and does not get published
  - [http://grad.msu.edu/researchintegrity/resources/peerreview.aspx](http://grad.msu.edu/researchintegrity/resources/peerreview.aspx)
Uses of Peer Review

- Guidance committee determination whether a thesis or dissertation satisfies degree requirements
- Editorial board decisions about which manuscripts should be published in a professional journal, as a chapter, or as a book
- Funding agency decisions about which research proposals should be funded
- Committee decisions about which submitted papers should be accepted for presentation at a conference
- Judges’ decisions about the quality of art work, music, or literature submitted to a competition or show

http://grad.msu.edu/researchintegrity/resources/peerreview.aspx
Ethical Principles for Reviewing

- **Fairness** – The reviewer must make every effort to provide an objective and impartial review.

- **Confidentiality** – The reviewer may not use ideas from the manuscript until it is published, and then only with an appropriate reference citation.

- **Speed** – Out of courtesy to the authors and respect for the scientific community, the reviewer should complete the review within a reasonable amount of time.
Confidentiality…

the state of being secret
How Confidentiality is used in Peer Review

- Reviewers must agree – this is not for sharing
- Editors must agree
- Study Sections must agree
- Scientific Review Officers must agree

Get the picture?
Publishers have to promise, too!

http://www.mscediting.com/service/confidentiality.html
CONFIDENTIALITY OF THE REVIEW PROCESS:

It is inappropriate for you, or anyone on your behalf, to contact a study section member (or potential member) regarding the review of your grant application either before or after the meeting of the study section. For a variety of reasons, reviewers are instructed not to discuss anything about the review with anyone.
PAUL HUNT

- EXPORT CONTROL
Export Control & Trade Sanctions

+ Welcome to the real, hard-edged world.

+ The U.S. government imposes export controls and trade sanctions for varying reasons.

  * control of technology for national security
  * protection of the oppressed (no torture)
  * suppression of crime (notably narcotics)
  * to control trade as a foreign policy lever
  * punishment

+ High Tech ➔ High Risk, per Regulations
Export Control -- Technology

1. Export controls are imposed through two sets of regulations: ITAR (applicable to all non-"U.S. persons" for military technology) and EAR (applicable according to citizenship for "dual use" items).

2. "Fundamental research" on a U.S. university campus is typically excluded from ITAR, and at U.S. university and R&D sites it is typically excluded from EAR provisions.

3. The "Fundamental Research Exclusion" (FRE) is lost for:
   a. Cryptography;
   b. If publication or citizenship restrictions apply;
   c. For in-bound controlled data or equipment;
   d. When research is conducted outside of the United States;
   e. If contracted prototypes or defense services.
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Export Administration Regulations

Bureau of Industry and Security

January 29, 2015
University Charged with Export Violations

BY: THOMAS B. MCVEY & JAHNA M. HARTWIG


The **University of Massachusetts at Lowell** was charged by the Bureau of Industry and Security ("BIS") for violating export control laws in connection with the export of an atmospheric testing device and related equipment. Specifically, the University was charged with … exporting items classified as EAR99 to a party on the BIS Entity List. This case reinforces the important point that even universities engaged in fundamental research are required to comply with export control laws. It also reinforces the importance of prohibited party list screening as a mandatory part of export compliance.
BIS Entity List

The U.S. (and in some cases the U.N.) forbids exports to, and/or other transactions with, certain people, institutions, and foreign governments.

- Sichuan University, China
- Bhabha Atomic Research Center, India
- D’s Supermarket, Corozal Town, Belize
- Kairaba Supermarket, Banjul, Gambia
- Dr. Ayman Al-Zawahiri

** For EC&TS assistance: please call 432-4499. **
Trade Sanctions

Treasury’s SDN list and Trade Sanctions imply, for example:

- MSU Dubai – don’t use Bank Melli (Iranian owned).
- MSU College of Music – careful during concert performance trips to Cuba.
- MSU USAID researchers – careful in Myanmar (Burma) project.

** For EC&TS assistance: Lori Hudson at 432-4499. **
MSU faculty wish to conduct funded research projects carrying publication or citizenship restrictions. Generally, MSU does not currently accept such projects, in the interest of maintaining an open campus environment for international scholarship.

Peer institutions have created University Research Organizations to house restricted projects securely, apart from their traditional open campuses. As of June 2012, MSU did so, too.
Six caveats advanced by governance

1. General funds will not be used to establish the URO.
2. Classified research will not be conducted at the URO.
3. The openness of the campus to international scholars will be preserved.
4. Research will be allowed at the URO only if it cannot be conducted traditionally on the MSU campus.
5. The current MSU policy on open publication of research results will be strengthened for regular projects on campus.
6. Undergrads, graduate students, and junior faculty will receive written and disinterested oral explanations of the career implications of URO participation.
Placing a project in the URO requires:

- A project impermissible in traditional academic units, but permissible for the URO.
- The agreement of all Principal Investigators, their departments/schools and colleges, and the URO itself.
- Conduct of the project in URO space. (Typically MBI Building or else 2727 Alliance Drive; exceptions for immovable equipment.)
- **Compliance with the URO Access Control Plan.**
- Citizenship eligibility of participants.
- Arm’s length advising of all junior personnel, pre-involvement.
EC&TS

Issue

Escalation

▶ When in serious doubt, ask – starting with your preceptor.

▶ OVPRGS staff can help, any time, day or night, whether you are here or abroad.

  Daytime, M-F: 432-4499
  Otherwise: 285-5646

▶ Failure to escalate some issues can be a “career crash landing”.
To talk about with RIC

- Can you identify any conflict of interest in your world right now?
- In considering your thesis or postdoctoral research, do you need to think about export control?
Pre-Workshop Readings

Write your Name on Card &

one example of a potential conflict of interest (personal, financial) in your scientific world
Research/Scholarly Integrity Resources

- The Graduate School
  - [http://grad.msu.edu/researchintegrity/resources/](http://grad.msu.edu/researchintegrity/resources/)
- University Task Force on Research Mentoring. 2004. *Guidelines for Graduate Student Advising and Mentoring Relationships*
  - *Guidelines for Integrity in Research and Creative Activities*
Sources


FUTURE RCR WORKSHOPS

- The one and only Jim Pivarnik (RIO)
- February 10, 2016 – Research Misconduct