## Responsible Conduct of Research Workshop Series, 2016-2017

Peer Review/Conflict of Interest March 2, 2017

## 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."
  - 2009. On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition. p2.



## **Two Areas of Emphasis**

# Conflicts of Interests Peer Review/minimizing Bias





- Define "financial conflict of interest" and give actual or hypothetical examples from <u>your</u> discipline
- Define "conflict of commitment" and give actual or hypothetical examples from <u>your</u> 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



Hurst, S. A. & Mauron, A. (2008). A question of method: The ethics of managing conflicts of interest. *EMBO Reports*, 9(2), 119-123, doi:10.1038/sj.embor.2008.4

... 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."



#### **News:** Federal Audit Faults Universities Over Researchers' Financial Conflicts of Interest, The Chronicle of Higher Education, 11/19/09

"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."



#### 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." Conflict of Interest in Medical Research, Education, and Practice, http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx
  - 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, <a href="http://ori.dhhs.gov/education/products/RCRintro/">http://ori.dhhs.gov/education/products/RCRintro/</a>



#### Financial Conflicts, continued

According to federal regulations, <u>financial conflicts of interest</u> 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 <a href="http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm">http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm</a>



### MSU start ups...some examples





BIOPHOTONIC SOLUTIONS, INC. LIFEBLOOD

NAMESFORLIFE	PHENOMETRICS



#### **Financial Conflicts:**

#### **MSU Financial Conflict of Interest Policy**

http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/facultyCOI.htm

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/

- <u>Disclosure</u> 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
- <u>Significant financial interest</u> 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.
- <u>Review, management, and resolution of reported conflicts of</u> <u>interest</u> – the unit administrator must take a leadership role
- <u>Michigan Contracts of Public Servants with Public Entities Law</u> 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 \$9.3million, 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.

Monastersky, R. (2008). Conflict-of-Interest Concerns Halt NIH Chronicle of Higher Education, http://chronicle.com/article/Conflict-of-Interest-Concer/1249/

> Responsible Conduct of Research, Scholarship, and Creative Activities Michigan State University Graduate School, 2010 http://grad.msu.edu/

# **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 <a href="http://www.nature.com/authors/editorial\_policies/competing.html">http://www.nature.com/authors/editorial\_policies/competing.html</a>

Responsible Conduct of Research, Scholarship, and Creative Activities Michigan State University Graduate School, 2010 http://grad.msu.edu/

#### 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 postdoctoral trainee?



#### RCR Topic: Conflict of Interest

Title: Show Me The Money!

**Case:** Dr. Galloway's lab has been studying the effect of certain compounds on high blood pressure. Mr. Conte, a representative from Drug Inc., has approached him about doing a study on Compound Q, a natural compound found in some plants that may lower the blood pressure of patients with chronic high blood pressure.

- Dr. Galloway is a world-renowned pharmacologist, and is well respected within his field. When he publishes a study, people tend to take notice. However, as with everybody during these tough economic times, he is having trouble bringing in the money to fund his research.
- Drug Inc. is willing to fund this 100% of the costs associated with this study. Although nothing is put into writing, Mr. Conte hints that if the outcome appears beneficial, the company would be willing to fund future studies in Dr. Galloway's lab.
- Dr. Galloway has actually been following Drug Inc. and several of their products for several years, and believes that many of their products show promise. Because of this, and unbeknownst to Mr. Conte and Drug Inc., Dr. Galloway carries a small amount of stock in the company.

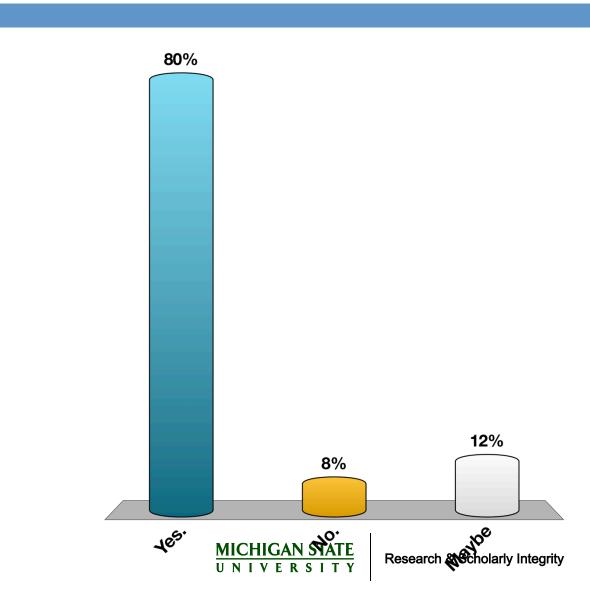
Dr. Galloway decides to go ahead and pursue the study. Since he wants to avoid issues associated with a conflict of interest, he assigns a valued postdoctoral fellow to serve as PI for the project, although Dr. Galloway is still involved with some of the data analyses. The study shows that the product being tested likely has positive benefits, and Galloway's lab publishes these results. In the following years, Dr. Galloway's lab conducts several other studies that are funded by Drug Inc.

#### **Discussion Questions**

- According to MSU policies, does Dr. Galloway have a conflict of interest that should have been disclosed to the university and to everyone else involved with this study?
- 2. Is Dr. Galloway avoiding this conflict of interest by assigning someone from his lab to do the actually study and not doing it himself?
- 3. Was it wrong for Mr. Conte to suggest to the Galloway lab that positive results would likely lead to future funding?
- 4. Where could Dr. Galloway and others learn more about conflicts of interest in research?

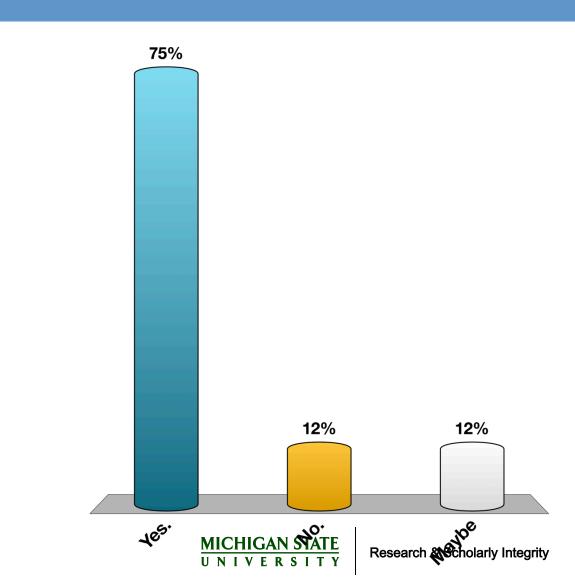
## Dr. Galloway has a conflict of interest.

- 1. Yes.
- 2. No.
- 3. Maybe



#### The postdoc has a conflict of interest.

- 1. Yes.
- 2. No.
- 3. Maybe



#### **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:

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
  Responsible Conduct MICHIGAN STATE In and Creative Activities Research & Scholarly Integrity

Michigan State UniversityUGNadWate BcSob

## All faculty must Annually Disclose



#### Questions about Conflict of Interest

- MSU Faculty Conflict of Interest Policy <u>http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/</u> <u>facultyCOI.htm</u>
- MSU Faculty Conflict of Interest Handbook <u>https://www.msu.edu/~biomed/COI/COIHandbook.html</u>
- MSU Conflict of Interest Information Officer
  - Brian Mattes 105D Olds Hall Phone 517-884-7000 Email fcoiio@msu.edu



#### Sources

MSU Faculty Conflict of Interest Policy <u>http://www.hr.msu.edu/documents/facacadhandbooks/facultyhandbook/</u>

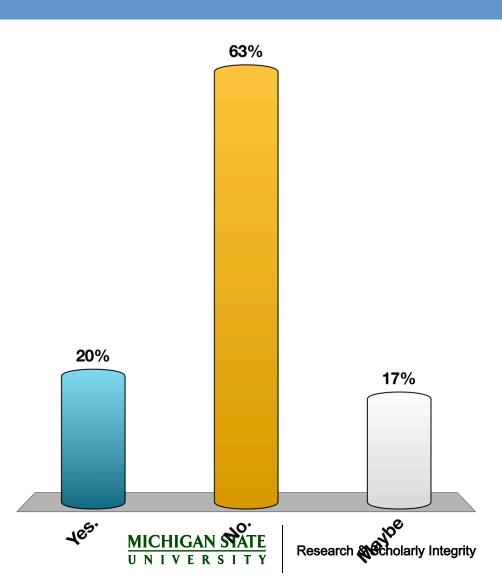
facultyCOI.htm

MSU Faculty Conflict of Interest Website <u>http://coi.msu.edu/</u>

> Responsible Conduct of Research, Scholarship, and Creative Activities Michigan State University Graduate School, 2010 http://grad.msu.edu/

# I have a conflict of interest.

- 1. Yes.
- 2. No.
- 3. Maybe



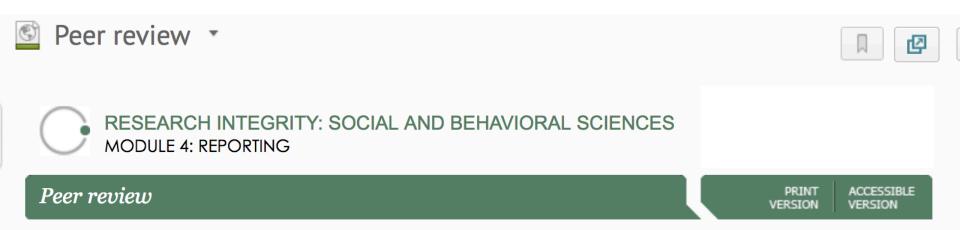
# JUDGING QUALITY RESEARCH / SHOLARSHIP

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."
  - http://en.wikipedia.org/wiki/peer\_review
- 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





#### Always review others' work as fairly and carefully as you would want them to review your own.



# **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



#### Take them to Pharm Rev site....





#### 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?

http://www.google.com/imgres?hl=en&client=firefox-a&hs=aPs&sa=X&rls=org.mozilla:en-US:official&biw=1311&bih=791&tbm=isch&prmd=imvns&tbnid=EqY3CqFIHRaY3M:&imgrefurl=http:// seekingalpha.com/article/178406-fed-policy-see-no-evil-hear-noevil&docid=TSX0u1zrQyWnUM&imgurl=http://static.seekingalpha.com/uploads/2009/12/16/ saupload\_policymakers.jpg&w=800&h=600&ei=GUYZT42GD9TyggfM6KT6Cw&zoom=1&iact=hc&vpx= 288&vpy=192&dur=331&hovh=149&hovw=200&tx=125&ty=61&sig=106772504118138767509&pa ae=1&tbnh=132&tbnw=178&start=0&ndsp=24&ved=1t:429,r:1,s:0





# Publishers have to promise, too!

MACMILLAN						
SCIENTIFIC COMMUNICATIONS	Our service 💌	Our editors	About MSC	FAQ	Contact us	
Home » Our service » Confidentiality						

#### Confidentiality

We take every step to ensure that your data is secure with us and that your unpublished results are treated confidentially. All our editors sign strict confidentiality agreements that prevent them from making use or disclosing any material that is handled by them during the MSC Scientific Editing service. Furthermore, only MSC staff will have access to author information; all author information will be removed from manuscripts before being passed on to the developmental and language editors. We value your trust and ensure all measures are taken to treat your manuscript in a secure and confidential manner.

#### **Our service**

About the service Sample edits Submit a paper Terms of Service Confidentiality

Exclusive partner to the publishers of Nature and Scientific American



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.

#### http://ora.msu.edu/RCR-ORA-tracked

#### **Office of Regulatory Affairs**

VPRGS	FUNDING	PROPOSAL PREPARATION C	COMPLIANCE	COMMERCIALIZAT	TION RESOURCES	EDUCATION	UNITS			
ORA Annou	incements	RCR Tracking in Saba LMS								
Board Comm	s & nittees	<b>Viewing Training Records</b> There are several ways completion records can be accessed. The best method depends on:								
ORA L	Jnits	your relationship to the student (e.g. manager, instructor), the number of students you'll								
RCR		need to monitor (3 versus 300), etc. Some units may choose multiple options. FERPA rules apply.								
Trainiı	ng	Student/Employee Trainees	s Supervisors	Primary Investigators*	Unit Administrators					
Conta	ct Us		KICHIGAN STATE UNVERSITY TRAINU							
<b>Y</b>		Final a screeenshot	* Research or managers, c	erical support staff and rock y view other	Sample prepared reports: Ad Hoc STUDENT Certifications CITI Course Completions Grad School RCR Workshop					

Contact the ORA regulatory training system Helpdesk for assistance in setting up views or reports on your student RCR records. Contact the Helpdesk to discuss recording additional training in the system.

Earning your Certificate for RCR (prior to 2016)

- YOUR DEPARTMENT decides whether or not you are required to obtain a certificate
- Must have attended all the workshops (Human OR Animal)
- Must have obtained an avg of a 75% score on collective assignments
- Certificates will be sent to your department
- Your department will give you your certificates



## Research/Scholarly Integrity Resources

- The Graduate School
  - http://grad.msu.edu/researchintegrity/resources/
- University Task Force on Research Mentoring. 2004.
   <u>Guidelines for Graduate Student Advising and Mentoring</u> <u>Relationships</u>
  - Guidelines for Integrity in Research and Creative <u>Activities</u>



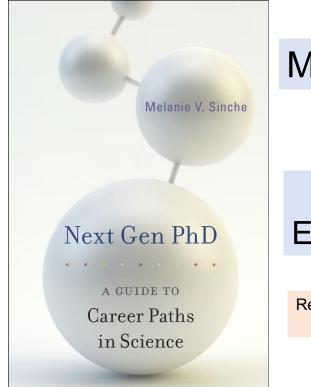
## FUTURE RCR WORKSHOPS

#### Research & Scholarly Integrity

<u>http://grad.msu.edu/researchintegrity/</u>



Science Graduate Students, Postdoctoral fellows and Mentors! SAVE THE DATE!

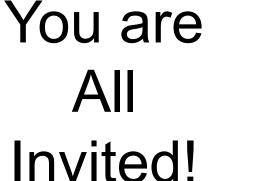


May 31, 2017

3-4 pm

The Kiva Erickson Hall

Registration online (free) will open by April 15 2017





How can you maximize your time in graduate school and/or during postdoctoral training? What strategies can you use for landing the right occupation? This presentation will provide an up-to-date assessment of the current career landscape facing science PhDs. Author Melanie Sinche will share proven strategies based on her research and profiles of science PhDs across a wide range of disciplines. Her research identified transferable skills from PhDs and career paths in a range of options, including education, industry, and non-profits.

**Melanie V. Sinche** is director of education at The Jackson Laboratory for Genomic Medicine. Her book Next Gen PhD: a Guide to Career Paths in Science <<u>http://www.hup.harvard.edu/catalog.php?isbn=9780674504653</u>> was recently published by Harvard University Press. Ms. Sinche is also a certified career counselor with extensive experience working with graduate students and postdocs across the country.

#### Sponsored by:



MICHIGAN STATE UNIVERSITY

The Graduate School