Welcome to UMB’s PHS Training Module for PHS- Funded Investigators

Please review this power point presentation and complete the training assessment following the presentation. The Assessment must be completed to satisfy this training requirement. Thank You.
To All PHS Investigators

• New regulations pertaining to financial conflicts of interest in research sponsored by the U S Public Health Service (PHS) went into effect on August 24, 2012. These regulations, Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought, found at www.gpo.gov/fdsys/pkg/FR-2011-08-25/html/2011-21633.htm, differ significantly from the regulations they are replacing in the following ways:
  – The new regulations now require investigators to disclose all significant financial interests\(^1\) relating to their UMB responsibilities and UMB is then responsible for determining whether or not the financial interest is related to PHS-funded research and poses a potential conflict of interest.
  – The new regulations lower the threshold from $10,000 to $5,000, but the regulations require institutions to apply stricter specifications, if stricter specifications are in effect at the institution. Due to State of Maryland requirements, therefore, there will be no lower threshold at UMB. All significant financial interests will need to be disclosed.
  – Failure by UMB to report financial conflicts of interest to the PHS awarding component in a timely manner will necessitate a retrospective review of research to determine whether or not the design, conduct or reporting of the research was biased.
  – The new regulations require all Investigators to receive training in the PHS regulations and in UMB’s policy and procedures covering the new regulations.
  – Information about each financial conflict of interest may be posted to a publicly accessible UMB web page.

• UMB’s Policy and Procedures on Financial Conflict of Interest to Promote Objectivity in Public Health Service-Funded Research may be found at http://cf.umaryland.edu/umpolicies/usmpolicyInfo.cfm?polid=382. This policy does not replace the existing USM Conflict of Interest policy and UMB procedures implementing that policy. Rather, the new policy covers conflicts of interest in PHS-funded research at UMB.

\(^1\)Significant Financial Interests include remuneration during the past twelve (12) months from a publicly traded entity or a non-publicly traded entity; income from intellectual property rights, except such income paid through the University; and reimbursed or sponsored travel, except by Federal, state or local governments, higher education institutions, academic medical centers or teaching hospitals, or research institutes affiliated with higher education institutions.
List of U.S. PHS Funding Agencies

- AHRQ  Agency for Healthcare Research and Quality
- ATSDR  Agency for Toxic Substances and Disease Registry
- CDC  Centers for Disease Control and Prevention
- FDA  Food and Drug Administration
- HRSA  Health Resources and Services Administration
- IHS  Indian Health Services
- NIH  National Institutes of Health
- SAMHSA  Substance Abuse and Mental Health Services Administration
Applicability

- PHS-supported research
- All individuals involved in the research
- Grants or contracts with an issue date on or after August 24, 2012
- **Exception** - Small Business Innovation Research Program (SBIR) and Small Business Technology Transfer Program (STTR) **Phase I applications**
Example of a Notice of Award

(Check Issue Date for Applicability: August 24, 2012 or later)
Requirements

- **Investigator** Training before research begins and every four years
- **Investigator** Disclosure of Significant Financial Interests (SFIs) to University
- Determination of **Financial Conflicts of Interest (FCOI)** by University
- Development of **Management Plan**
- Reporting FCOIs to PHS awarding agency before funds are expended by University
UMB Procedures

• Online training

• Disclose SFIs (or lack thereof)
  – Annually, as they develop or change, at time of proposal submission
  – You must submit a SFI Form even if you have nothing to disclose
  – The SFI Disclosure Form, and instructions for completing it, can be found by clicking on the link below.
    – Submit SFI Disclosure Form via e-mail at Disclosure@umaryland.edu
    – PHS Online Disclosure system is in development

• Determination of FCOI (or lack thereof)

• Development of Management Plan
  – By CoI Officer, in collaboration with Investigator and Department Chair

• Reporting to PHS Awarding Agency
Investigator Training

• **When?**
  – Prior to Investigators engaging in research
  – Every 4 years thereafter
  – Again, remediating non-compliance

• **What?**
  – PHS FCOI regulations
  – Institution’s CoI policy
  – Investigator’s responsibilities
Disclosure of All Significant Financial Interests

• Investigators must disclose all SFI related to their institutional responsibilities, regardless of the SFI’s relationship to their PHS-sponsored research
Examples of Financial Interests that **must be disclosed**

- Remuneration of any value during the 12 months prior to your disclosure, from any entity, such as:
  - Consulting or Speaking fees
  - Honoraria
  - Salary or Wages
  - Paid Authorship

- Intellectual Property-related income (such as royalty payments from patent licensing), except that which is received through the University

- Equity interest in any entity (such as stock or stock options)

- Any reimbursed or sponsored travel during the 12 months prior to your disclosure

- Financial Interests in professional and scientific societies
Financial Interests that are **not required** to be disclosed

- Salary, royalties, or other remuneration paid by UMB
- Income from investment vehicles (such as mutual funds) as long as Investigator does not directly control the investment decisions
- Asset in a blind trust, if investigator does not know of the asset and trust is managed by an independent fiduciary
- Income from seminars, lectures, teaching engagements, service on advisory committees or review panels sponsored by a federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education
SFI Disclosure Information

(Required Information for disclosing a Significant Financial Interest)

- Name of Investigator
- E-mail address
- Entity
- Type of Financial Interest
- Amount (Value) of Interest
- Date(s) of Interest
- Description of Financial Interest
- Relationship of Financial Interest to PHS-sponsored research
- Include relevant documents
Disclosure for Reimbursed Travel

(Required Information for disclosing Reimbursed Travel)

• Purpose of trip
• Identity of the Sponsor/Organizer
• Destination
• Duration
University Determines Financial Conflict of Interest (FCOI)

• Is the SFI related to PHS-sponsored research?
  – SFI affected by the research?
  – Entity’s financial interest affected by the research?

• Does the SFI constitute an FCOI?
  – Could it directly and significantly affect the design, conduct or reporting of the research?
FCOI Must be Managed

• When a FCOI has been identified, that FCOI must be managed.

• A management plan should provide reasonable expectation that the research will be free from bias due to that FCOI.
FCOI Scenario and Management Plan

• **FCOI SCENARIO**
  – You are a paid consultant to a pharmaceutical firm which markets a compound that is subject of NIH-sponsored research in which you are involved.

• **FCOI PROBABLE MANAGEMENT PLAN**
  – Disclosure
  – Research design measures to reduce or eliminate bias
  – Annual review with Dept Chair
FCOI Scenario and Management Plan

**FCOI SCENARIO**

– You own equity in a company which markets a compound that is a subject of your NIH-sponsored research

**FCOI PROBABLE MANAGEMENT PLAN**

– Disclosure
– Research design measures to reduce or eliminate bias
– Annual review with Department Chair
– Oversight of research and publications by Department Chair or Designee
University Reports (Managed) FCOI to PHS

- Prior to expenditure of research funds
- Within 60 days of identifying new FCOI
- Annual Updates
Consequences for Non-Compliance

• **Failure to receive training**
  
  – You cannot work on the research until you have been trained.
  
  – For Principal Investigators or Program Directors, the research project will be on hold until you have received training.
Consequences for Non-Compliance

• **Failure to disclose SFI**
  – You cannot work on the research until you have submitted a SFI form.
  – What if you submitted a SFI Form but did not disclose a SFI that should have been disclosed. Penalties will depend on the reason for not disclosing:
    • If you did not know about the SFI, usually no penalties.
    • If you did not understand that the SFI was an SFI, probably repeat PHS training requirement.
    • You intentionally did not disclose, this will be considered non-compliance, will require a repeat of this training module, and other possible disciplinary actions.
Consequences for Non-Compliance

• Failure to report FCOI
  – University must review the research that has been conducted while you had the FCOI
    • Determine the effect of your FCOI on the research
    • Prepare Management Plan
    • Report FCOI to PHS awarding agency
    • Additional penalties depend on reason for not reporting the FCOI
Consequences for Non-Compliance

• Failure to comply with a Management Plan
  – Repeat training
  – Possible disciplinary action, depending on the reason for non-compliance
UMB’s Policy and Procedures on Financial Conflict of Interest to Promote Objectivity in Public Health Service-Funded Research

HTTP://CF.UMARYLAND.EDU/UMPOLICIES/USMPOLICYINFO.CFM?POLID=382
For Further Assistance, please contact

Alison Watkins athom001@umaryland.edu
Research Integrity Office
Office of Accountability and Compliance
Academic Affairs

http://www.umaryland.edu/offices/accountability/research_integrity.html
Thank You for participating in this Training Exercise.

• Please continue to the training assessment to complete training.

• Please click link below for training assessment http://cf.umaryland.edu/academic_affairs/RIO_quiz.cfm

• Successful completion of this training requirement will be automatically sent to UMB’s Research Integrity Office.

• We welcome your feedback on this training module. To do so, please send an email to Disclosure@umaryland.edu.