



NEW FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATORY REQUIREMENTS

APRIL 30, 2012

**THORU PEDERSON, PH.D., ASSOCIATE VICE PROVOST FOR RESEARCH
ELIZABETH DELGADO RODRIGUEZ, ASSOCIATE COUNSEL**

FCOI REGULATIONS - FINAL RULE

- Rule published 8/25/11 revises the regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- Implementation required no later than 365 days after publication of the final rule in the Federal Register, i.e., 8/24/12.
- In the interim:
 - Institutions comply with 1995 regulations, revise policies, establish procedures for compliance, and train Investigators
- New UMMS FCOI policy will go live 8/1/12.

WHAT IS THE PURPOSE OF THE REGULATION?

- The regulation is aimed at ensuring that the design, conduct, or reporting of research funded under PHS grants and cooperative agreements will not be biased by any conflicting financial interest of the Investigators responsible for the research.

MAJOR CHANGES TO THE 1995 REGULATIONS INCLUDE:

- More inclusive definition of Investigator
- Lower financial disclosure thresholds
- New conflict of interest training requirement
- Increased transparency for travel reimbursement
- Detailed information reported to PHS
- Information made accessible to the public

DEFINITION OF INVESTIGATOR

1995

- Anyone involved in the design, conduct, and reporting of the research

2011

- Project Director/Principal Investigator as well as any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which includes subawardees and may include collaborators or consultants

SFI vs. FCOI

- A significant financial interest (SFI) is one that could directly and significantly affect the design, conduct, or reporting of funded research
- A Significant Financial Interest (SFI) is not always an FCOI
- An FCOI exists when a designated Institutional official reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of the funded research

SIGNIFICANT FINANCIAL INTERESTS (SFI) THRESHOLD

1995

- De minimis threshold of \$10,000 for disclosure generally applies to payments aggregated for the Investigator and the Investigator's spouse and dependent children
- Equity: An equity interest that exceeds \$10,000 in value or more than a 5% ownership interest in any single entity

2011

- De minimis threshold of \$5,000 for disclosure applies to any remuneration received from the entity aggregated together with the value of any equity interest.
- Includes any equity interest in non-publically traded entities
- The COI threshold for research involving human subjects is \$0 and subject to UMMS Human Subjects Guidelines

WHICH SFIS NEED TO BE DISCLOSED ONCE THRESHOLD IS MET?

1995

- Only those SFI the Investigator deems related to the PHS-funded research

2011

- All SFI related to the Investigator's institutional responsibilities
- Updates required within 30 days of change or occurrence (travel)

EXCLUDED FROM DISCLOSURE REQUIREMENT

1995

- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; income from service on advisory committees or review panels for public or nonprofit entities
- Combined equity interest for the Investigator, their spouse and dependent children that doesn't exceed \$10K in value and doesn't represent more than a 5% ownership interest in any single entity.

2011

- Income from seminars, lectures, or teaching engagements, or service on advisory committees or review panels sponsored by:
 - Federal, state, or local government agencies
 - Institutions of higher education
 - Academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.
- Income or service for any other type of organization must be reported.

SBIR/STTR PHASE I GRANTS

1995

- Excluded

2011

- Excluded

INTELLECTUAL PROPERTY (IP)

1995

- Royalties are included among the “payments” subject to the \$10,000 threshold.

2011

- The threshold of \$5,000 applies to licensed IP rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to licensed intellectual property rights.
- When? Upon filing of a patent application or receipt of income related to such rights and interest, whichever comes first.
- Excluded: Unlicensed IP that doesn't generate income; IP rights assigned to the Institution and agreements to share in royalties related to such rights

TRAVEL REIMBURSEMENTS AND SPONSORED TRAVEL

1995

- Not included

2011

- Disclose the occurrence of any reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration).
- NOT required to disclose travel that is reimbursed or 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.
- Does not require disclosure of the monetary value of the travel . The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

SUBRECIPIENTS AND REPORTING OF IDENTIFIED FCOIs

1995

- Institutions must take reasonable steps to ensure Subrecipient Investigators comply with the regulations by requiring those Investigators to comply with the institution's policy, or by providing assurances that will enable the institution to comply

2011

- Include in subaward whether the policy of the prime recipient or that of the subrecipient will apply to and include time periods to meet disclosure and/or reporting requirements
- Subrecipients that rely on their FCOI policy must report identified FCOIs to the prime recipient with sufficient time so the prime can meet NIH reporting obligations.

FCOI TRAINING

1995

- No requirement

2011

- Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the following circumstances:
 - If institutional FCOI policies change in a manner that affects Investigator requirements, an Investigator is new to an Institution, an Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.

PUBLIC ACCESSIBILITY REQUIREMENT

1995

- No requirement

2011

- Make identified FCOI information via a publicly accessible web site or by a written response to any requestor within 5 business days of a request
- Minimum Information to Provide:
 - Investigator name, title and role
 - Name of the entity in which the SFI is held
 - Nature of the SFI
 - The approximate dollar value of the SFI
 - (or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value)

APPLICATION DATE OF FINAL RULE

- No later than August 24, 2012 and immediately upon making the institutional FCOI policy publicly accessible.
- UMMS go live date will be August 1, 2012
- The revised regulations will apply to each grant or cooperative agreement with an issue date on the NOA that is after the go live date and to solicitations issued and research contracts awarded after the go live date.