



IMPLEMENTATION OF NEW FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATORY REQUIREMENTS

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DIEGO VAZQUEZ, RESEARCH FUNDING SERVICES

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.
- New UMMS FCOI policy will go live 8/1/12.
 - New UMMS policy covers all sponsored project activity (not just PHS/federal)

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 REGULATIONS INCLUDE:

- More inclusive definition of Investigator
- Lower financial disclosure thresholds (\$5K instead of \$10K)
- New conflict of interest training requirement
- Increased transparency for travel reimbursement
- Detailed information reported to PHS when conflicts exist
- Information made accessible to the public

DEFINITION OF INVESTIGATOR

- 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 or proposed for such funding, which includes subawardees and may include collaborators or consultants.

SUBRECIPIENTS AND REPORTING OF IDENTIFIED FCOIs

- Proposal Stage
 - Subrecipient will provide assurance that they have policies that comply with sponsor regulations
- Award Stage
 - UMMS subrecipients must have their own FCOI policy (UMMS will not allow UMMS policy to apply to subrecipient)
 - Subrecipients must report identified FCOIs to UMMS so we can meet NIH reporting obligations.

FCOI REQUIREMENTS AT THE PROPOSAL STAGE

- A Summary Disclosure of Financial Interests (SDFI) form must be submitted with each application.
- The SDFI is a project-based (not individual-based) disclosure form.
- All individuals meeting the new definition of Investigator are required to complete the disclosure.

THE SDFI FORM

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University of Massachusetts Medical School Summary Disclosure of Financial Interests

Proposal ID#:

Completion of this form is **mandatory** for all proposals. This information is required to comply with the University of Massachusetts Medical School Policy for Promoting Objectivity in Biomedical Research and applicable federal and state laws and regulations regarding timely and proper disclosure of financial interests.

Principal Investigator Name: Last, First, MI <input type="text"/>	Principal Investigator Title: <input type="text"/>	Department: <input type="text"/>
Sponsor: <input type="text"/>	Project Start Date: <input type="text"/>	Project End Date: <input type="text"/>
Project Title: <input type="text"/>		

- A. The Project Principal Investigator is responsible for determining who meets the definition of an "Investigator" on their project and certifies that this form provides:
- a complete disclosure of all Investigators responsible for the design, conduct, or reporting of activities associated with this project, and
 - an accurate report of the current state of the named Investigator's disclosure in the institution's electronic reporting system.
- Principal Investigator agrees to update the UMMS COI system annually during the period of the award and within 30 days of discovering or acquiring a new Significant Financial Interest.

Principal Investigator Disclosure & Certification

Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests (SFI) related to the Investigator's Institutional Responsibilities? (Reference definitions on the reverse side of this form).

☐ Yes ☐ No If yes, investigator confirms the disclosure on the UMMS COI System (<https://coi.umassmemorial.org/coi/>) has been updated and is current.

Signature of Principal Investigator

Date

Disclosures & Certifications for UMass Personnel Identified as "Investigators"

- B. For the purposes of this disclosure, **Investigator** is defined as any person, **regardless of title or position**, who is responsible for the design conduct, or reporting of research, or proposed for such funding, which includes subawardees and may include consultants and unpaid collaborators.

By signing below each Investigator (1) certifies that this form provides an accurate report of whether there are any Significant Financial Interests related to their Institutional Responsibilities, and (2) acknowledges responsibility to provide a complete disclosure of all Significant Financial Interests reasonably related to their Institutional Responsibilities prior to award receipt, as those interests change, and on an annual basis during the project award period.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Do you, your spouse/domestic partner or dependent children have any Significant Financial Interests (SFI) related to the Investigator's Institutional Responsibilities? (Reference definitions on the reverse side of this form).

1. ☐ Yes ☐ No If yes, investigator confirms the disclosure on the UMMS COI System (<https://coi.umassmemorial.org/coi/>) has been updated and is current.

Disclosing Investigator: Title:
Signature _____ Date _____

2. ☐ Yes ☐ No If yes, investigator confirms the disclosure on the UMMS COI System (<https://coi.umassmemorial.org/coi/>) has been updated and is current.

Disclosing Investigator: Title:
Signature _____ Date _____

3. ☐ Yes ☐ No If yes, investigator confirms the disclosure on the UMMS COI System (<https://coi.umassmemorial.org/coi/>) has been updated and is current.

Disclosing Investigator: Title:
Signature _____ Date _____

4. ☐ Yes ☐ No If yes, investigator confirms the disclosure on the UMMS COI System (<https://coi.umassmemorial.org/coi/>) has been updated and is current.

Disclosing Investigator: Title:
Signature _____ Date _____

(Attach additional disclosure certifications as required for all project Investigators.)

- C. ☐ Yes ☐ No Will **Non-University Investigators** be responsible with the PI or Co-PI for the design, conduct or reporting of the activities associated with the project (e.g., subcontractors, consultants, collaborators, others with significant responsibilities)?

If yes, UMMS must be assured that the Investigators' home institution(s) have policies that comply with the sponsor's regulations. Such assurance should be provided along with the participant's Letter of Intent/Commitment to the project at the submission stage.

Header/Proposal Info

Section A PI Disclosure

Section B: Investigator Disclosures

Section C: Non-University Investigators

THE SDFI FORM

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Form Instructions

Definitions

Review Process & Guidelines

Instructions

For all Proposal Submissions:

1. The Principal Investigator (PI) and each Investigator must sign the Disclosure Summary at the point of each proposal submission & confirm no change in status at the point of each award. Awards will not be processed by Research Funding Services until the Investigators have reaffirmed their disclosure status.
2. Investigators disclosing a Significant Financial Interest that is reasonably related to the Investigators' Institutional Responsibilities must update the UMMS COI System (<https://coi.umassmemorial.org/coi/>). The Associate Vice Provost for Research will review the SFI and determine whether an FCOI exists, and if necessary, make a recommendation to the Vice Provost for Research prior to award acceptance.
3. Submission of this form is also required on an annual basis for non-competing continuation awards, when a new Investigator is added to a project, or when an Investigator's financial interests increase, whichever comes first.
4. Any project that involves human subjects research is subject to the requirements of the University of Massachusetts Guidelines for the Oversight of Individual and Institutional Financial Interests in Human Subjects Research ("Human Subjects Guidelines"). Any amount of remuneration or any equity ownership related to a human subjects study requires additional reviews and oversight. See <http://media.umassp.edu/massedu/policy/Col%20Intellectual%20Policy%20Guidelines%20UMW%205-1-12.pdf>.

Definitions

Who Must Disclose? All individuals responsible for the design, conduct, or reporting of the results of work performed or to be performed under the sponsored project, referred to as "Investigator." Investigator includes, but is not limited to the Principal Investigator, Co-Investigators, and any other individuals (including personnel from other institutions) who are involved in accomplishing project objectives. It may include students, graduate and undergraduate, and other personnel who may be listed as authors on project results, even if they are not paid from the project.

What is a "Significant Financial Interest"? Any of the following payments:

1. With regards to **Publicly-Traded Entities**, payments or value exceeding \$5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity, including salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest) during the prior 12 months.
2. With regards to **Privately Held Entities**, payments or value exceeding \$5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity during the prior 12 months or when the Investigator and the Investigator's spouse/domestic partner and dependent children hold any equity interest (stock, stock option, or other ownership interest).
3. With regards to **Intellectual Property**, intellectual property rights and interests (patents, copyrights) **upon receipt of income** related to such rights and interests.
4. With regards to **Travel Reimbursements**, any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities during the prior 12 months (with the exception of 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).

The term "Significant Financial Interest" **does not include**: salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the Institution and agreements to share royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts; income from seminars, lectures, or teaching engagements 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 affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

What are "Institutional Responsibilities"? An Investigator's Institutional Responsibilities means the Investigator's professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Review Process and Guidelines

The Associate Vice Provost for Research will review affirmative Investigator disclosures in the institution's electronic reporting system. The Associate Vice Provost for Research will consider whether any of the disclosed Significant Financial Interests of the Investigator is related to the project and whether the financial interest could directly and significantly affect the design, conduct, or reporting of the project. The Associate Vice Provost for Research will coordinate with the University Conflicts Committee any review or approval required from that committee and develop a plan for management of any conflicts of interest.

Example: A direct effect would occur when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator has a Significant Financial Interest, or when the entity is a proposed subcontractor or participant in the project. A significant effect on the financial interest is one that will materially affect the value of the entity, its earnings, or sales of its products. The following are examples of when an Investigator would be deemed to have a **Financial Conflict of Interest (FCOI)**: (i) if the Investigator (together with the Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed grant/contract based on an analysis of the scope and subject matter of the proposed project described in the application, or (ii) the Investigator (together with the Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from the University which has resulted in license income and that the technology is the subject of a proposed grant/contract. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.

Retention of Information: Three (3) years after termination of sponsored project or until resolution of any action by the sponsor, whichever is greater.

SDFI FORM OVERVIEW

- Principal Investigator responsible for their own disclosure and determining who meets the definition of “Investigator” on their project
- Once Investigator determination is made, PI in conjunction with Department Administrator assistance will need to secure disclosures from the identified Investigators
- The SDFI is a project-based form (all disclosures will be captured on one form)
- All Investigator disclosures must be received in RFS before an application can be approved for submission

DISCLOSURE CLARIFICATION

- The SDFI form only captures whether an Investigator has a Significant Financial Interest (SFI)
- No detailed information regarding the nature of the SFI is disclosed on the SDFI
- Detailed SFI information is disclosed in the UMMS COI System (<https://coi.umassmemorial.org/coi/>)

WHAT HAPPENS WITH THE DISCLOSURE FORM?

- A copy of any SDFI with an affirmative disclosure of a Significant Financial Interest is forwarded to Dr. Thoru Pederson, the Associate Vice Provost for Research responsible for reviewing FCOI disclosures
- The original disclosure is kept in the proposal file and will be used to verify Investigator FCOI training at the JIT and award stages

FCOI TRAINING REQUIREMENT

- Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and must complete training 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.

FCOI TRAINING & AWARD SETUP

- For PHS supported projects, Investigators are required to complete their training obligations prior to engaging in research or by the issue date of the Notice of Award issued subsequent to the Institution's implementation date (August 1, 2012 for UMMS)
- RFS will confirm that individuals identified on the SDFI form have completed FCOI training before a project can be set up
- We recommend that all personnel paid off of sponsored projects take the training right away so that it does not slow down the award setup process when the next segment of funding is received

FCOI TRAINING - IMPLEMENTATION

- UMMS offers a specific FCOI training class that will satisfy the new regulatory requirement.
- FCOI training is offered through the CITI Online training module and can be accessed at <http://www.citiprogram.org/>.
- Investigators should take the mandatory training as soon as possible. Once taken the training is valid for four years. After four years, investigators will be required to take the training again.
- Instructions on how to create a CITI login and access the FCOI training module are available on the OVPR website at:
<http://www.umassmed.edu/fcoitraining.aspx?linkidentifier=id&itemid=157880>



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Financial Conflict of Interest

*****POLICIES GO INTO EFFECT AUGUST 1st, 2012*****

Effective August 1, 2012, the University of Massachusetts Medical School has implemented a Policy for Promoting Objectivity in Biomedical Research to comply with new federal financial conflict of interest reporting and training requirements. The new federal requirements are intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of sponsored research will be free from bias resulting from Investigator financial conflicts of interest.

Major changes include:

- A more inclusive definition of "Investigator"
- A revised disclosure process at the application stage
- Lower financial disclosure thresholds
- Disclosure of all activities relating to "Institutional Responsibilities"
- A requirement to disclose sponsored travel
- A new conflict-of-interest training requirement

The Office of the Vice Provost for Research has created this website to provide the UMMS research community with the resources needed to understand and manage this process.

FCOI Presentations and Resources:

Click [here](#) for a slide presentation detailing the new regulatory requirements.