Understanding Conflict of Interest Disclosure Obligations in Research

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Education Module Topics

This Module covers:

• what is a conflict of interest in research?
• when and how must a conflict be disclosed?
• what are the procedures for review of conflict of interest in research disclosures?
• what are the pertinent Division of Research ("DOR") policies?
Outside Activity/Conflict of Interest Disclosure Obligations Stem From

- Federal regulatory requirements
- State law requirements
- University policies
  - These policies capture your compliance obligations to disclose outside activities that may pose an actual or potential conflict
Conflict of Interest in Research on University Policy Library

http://policies.fiu.edu/

- Houses all official university policies and procedures, including all policies discussed here
- Links to policies also on DOR Web site
Conflict of Interest in Research on University Policy Library

What are the pertinent DOR policies?

• Conflict of Interest in Research
  http://policies.fiu.edu/record_profile.php?id=572

• Hiring and Paying Consultants on Sponsored Projects
  http://policies.fiu.edu/record_profile.php?id=351

• Identification of Special Handling Requirements for Proposal
  http://policies.fiu.edu/record_profile.php?id=268

• Subaward Preparation and Payment to Subrecipients on Sponsored Projects
  http://policies.fiu.edu/record_profile.php?id=367
FIU Conflict of Interest in Research Policy - Training Requirements

• FIU Conflict of Interest in Research Policy was recently revised to comply with the new U.S. Department of Health and Human Services Public Health Service (PHS) regulations effective 8/24/12.

• Investigators must complete training on this policy and on the PHS regulations regarding financial conflicts of interest:
  • Prior to engaging in any PHS-funded research and
  • At least 4 years thereafter and
  • Immediately if:
    • investigator requirements in the policy change
    • investigator is new to FIU or
    • investigator is non-compliant with policy or management plan
• Training is available online and you must register for such training through the FIU Division of Research, Office of Research Integrity

• Go to the web address for CITI: http://www.citiprogram.org

• As a "new" user, you will need to click "Register Here" to register for the training course

• Select "Florida International University" from the Participating Institutions

• Create a unique username, password, and security questions

• Enter your personal information (last name, first name, email) and additional information requested and then click “submit”

• When asked which course you plan to take, please select: "Conflict of Interest” and then click "continue"
What is conflict of interest in research?
FIU Conflict of Interest in Research Policy-Key Definitions

- Financial Conflict of Interest-a Significant Financial Interest (as defined by the PHS regulation) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research

- Investigator-the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research or of proposed research

- Research-a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g. a published article, book or book chapter) and product development (e.g. a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component or other sponsor through a grant or cooperative award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award
FIU Conflict of Interest in Research Policy-Significant Financial Interests (SFIs)

- “Significant Financial Interest” (SFI)-is the key definition that you must understand in order to comply with the federal regulations
- Significant Financial Interests are those of the Investigator, the Investigator’s spouse and dependent children that reasonably appear to be related to the Investigator’s institutional responsibilities:
  - Interest in publicly traded entities if the following interests, when aggregated among the Investigator and the Investigator’s spouse and dependent children, exceed $5,000:
    - any remuneration (e.g., salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria, paid authorship) received from the publicly traded entity by the Investigator and/or the Investigator’s spouse and dependent children in the twelve months preceding the disclosure plus
    - the value of any equity interest (including stock, stock options, or other ownership interest) in the publicly traded entity as of the date of the conflict disclosure.
FIU Conflict of Interest in Research Policy-Significant Financial Interests (SFIs) (Cont’d)

• Interest in non-publicly traded entities if:
  • the aggregated value of any remuneration received from any non-publicly traded entity by the Investigator and/or the Investigator’s spouse and dependent children in the twelve months preceding the conflict disclosure exceeds $5,000 OR
  • when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest in the non-publicly traded entity

• Intellectual Property rights and interests. Disclosure is required upon receipt of income related to such rights and interests except for royalties received from intellectual property assigned to the University
FIU Conflict of Interest in Research Policy-Significant Financial Interests (SFIs) (Cont’d)

- Travel must be disclosed as follows:
  - If it is reimbursed or sponsored travel related to the Investigator’s Institutional responsibilities and
  - The travel is sponsored or reimbursed from an entity that is not:
    - 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
Disclosure is required both when the amount of reimbursement or payment for the travel is known and when the exact monetary value is not known.

The details of travel disclosure must include, at a minimum:

- the purpose of the trip;
- the identity of the sponsor/organizer;
- the destination;
- the duration; and
- additional information may be required by the University’s Designated Official (who is the VP for Research or his designee).
The following financial interests are not considered SFIs under the federal regulations and therefore need not be disclosed in connection with the COI in Research Policy:

- salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement accounts, where the Investigator does not directly control the investment decisions made in those vehicles;
- 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 that is 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 that is affiliated with an institution of higher education.
How Are Interests Disclosed?

- Interests are disclosed by answering the questions on the Human Resources Outside Activities/Conflicts of Interest Electronic Portal available at: http://hr.fiu.edu/index.php?name=conflict_of_interest

- Adjunct faculty members and temporary staff members must disclose using the paper form which can be downloaded from that same webpage.

- Investigators who are not University employees (e.g. students, subcontractors, consultants or collaborators) must also use the paper form.
Whose Interests Must be Disclosed?

- All Investigators (see definition above) on proposed or existing research projects must disclose their Significant Financial Interests (SFIs) (see definition above)

- SFIs include those interests held by the Investigator, his or her spouse and dependent children
What Interests must be disclosed?

- Any Significant Financial Interest (as defined by the Federal regulation and University policy—see above) must be disclosed.

- Any material change in previously disclosed SFIs must be updated within 30 days of discovering or acquiring the new SFI.
When and how must a conflict of interest in research be disclosed?
When Must the Investigator Complete the Outside Activity/COI Disclosure?

(1) No later than the time a proposal for a sponsored research project is submitted to the Division of Research.

(2) An update disclosure must be submitted by September 30 each year (which must update any previously disclosed SFI).

(3) An updated disclosure is also required within 30 days of discovering or acquiring a new SFI (e.g., travel, purchase, marriage or inheritance).
How - Required Forms

How do you disclose your outside activities and financial interests related to a research proposal or project?

- Access and complete the electronic portal for Report of Outside Activity/Conflict of Interest (OA/COI). Note that the electronic portal is for use by all benefits eligible faculty and staff and completion of this form will comply with the research disclosure requirements.

- Adjunct faculty members, temporary staff, student interns and volunteers who are engaged in a research project and must disclose an outside activity/conflict of interest will continue to complete and submit the paper/hard copy of the OA/COI form which can be downloaded through this dedicated webpage.
In addition to the OA/COI portal disclosure, for all externally funded research projects the Investigator will also complete the COI questions on the Division of Research Electronic Proposal Routing Approval Form.

For Significant Financial Interests that arise after the proposal was submitted to an external sponsor, this SFI must be reported to DOR and also a new OA/COI electronic portal disclosure must be made.
Subawards

If there are any proposed subawardees (e.g. subcontractors, consultants), the Investigator must ensure that a Subawardee Commitment Form is completed for each subawardee.

The Subawardee Commitment Form identifies whether the subawardee has a COI policy that complies with the PHS regulations or if the subawardee will follow FIU’s policy.

If the subawardee commits to following FIU’s policy, the subawardee will need to complete the hard copy disclosure form that is available for downloading on the OA/COI Electronic Portal.
What happens after the Report of OA/COI is submitted?
Approval Routing
Approval Routing (Cont’d)

- The Outside Activity/COI review and approval process routing depends on whether the employee is a faculty member or staff member.

- At all stages of the review and approval process, the employee may be asked additional questions or consulted in order to obtain relevant information.
Approval Routing (Cont’d)

- **Faculty Disclosures**: If the disclosure is submitted by a faculty member, the direct supervisor (usually departmental chair) reviews the disclosure initially, followed by the dean or the dean’s designee (associate dean).

- If the disclosure involves research, the form is forwarded to the Vice President for Research or designee (hereinafter VPR) for review and approval. Upon the VPR’s approval, it is submitted to the Provost for final review and approval.
Approval Routing (Cont’d)

- **Staff Disclosures**: If the disclosure is submitted by a staff member, the direct supervisor reviews the disclosure initially.

- If the disclosure involves research, it is then forwarded to the VPR for review and approval. Upon the VPR’s approval, it is then submitted to the Vice President for Human Resources for final review and approval.
Routing of Academic Approval

- Office of the Provost
- Research
- Dean
- Direct Supervisor
- Faculty
- Review

Associate Dean
Routing of Administrative Approval

- Human Resources
- Research
- Direct Supervisor
- Admin/Staff
Review of Report of OA/COI Related to Research

- Prior to the commencement of any research project or expenditure of funds on any sponsored research project, the Designated Official (who is the VPR or his designee) reviews the Investigator’s disclosure of SFIs to determine whether any of the SFIs are related to the research and, if so, whether the SFI is a Financial Conflict of Interest (FCOI).

- If there is a FCOI, then the VPR may determine that the research project may not proceed or that it may proceed upon certain conditions that will be specified in a management plan.
Review of Report-FCOI addressed via Management Plan

- The VPR will specify what actions the Investigator must take in order for the FCOI to be addressed in a management plan. Such actions may include, without limitation:
  - Public disclosure of the FCOI (when presenting or publishing)
  - Direct disclosure to the participants in human subjects research
  - Appointment of an independent monitor
  - Modification of the research plan
  - Change of personnel or personnel responsibilities
  - Reduction or elimination of the financial interest (sale or divestiture of financial interest)
  - Severance of relationships that create the conflict
The VPR must provide to the sponsor a Financial Conflict of Interest Report when there is a determination that a Financial Conflict of Interest exists. This information must be updated on an annual basis.

For PHS funded projects such disclosures are done via eRA Commons. DOR facilitates completion of the online forms.

The elements of the FCOI Report include:

- Project number
- PI or Contact PI if a multiple PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has a FCOI
- Nature of the financial interest (e.g. equity, consulting fee, travel)
- Value of the financial interest (in dollar ranges)
- A description of how the financial interest relates to the PHS-funded research and the basis for the determination that there is a conflict
- A description of the key elements of FIU’s management plan
Retrospective Review - Mitigation

- If there is a Significant Financial Interest that is not timely discovered or disclosed, the Designated Official (who is the VPR or his designee) must conduct a retrospective review to determine if the SFI is a FCOI and if the FCOI has led to the collection and/or reporting of biased data.

- The retrospective review must be completed within 120 days and include the following elements:
  - Project number and title
  - PI or contact PI if a multiple PI model is used
  - Name of the Investigator with the FCOI
  - Name of the entity with which the Investigator has a FCOI
  - Reason(s) for the retrospective review
  - Detailed methodology used for the retrospective review
  - Findings and Conclusions of the review

- If the VPR determines that there has been bias, DOR will notify the PHS Awarding Component promptly and submit a mitigation plan. The mitigation plan must include the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the University’s plan of action to eliminate or mitigate the effect of the bias.
COI Issues when Contracting on Research Projects
Review Process Required by Florida Law for Researcher’s Proposed Contract

- If the transaction is one where a FIU researcher wishes FIU to enter into a contract with an entity in which the researcher has an interest (for research or intellectual property commercialization), Florida law requires that the contract must be specifically approved by the FIU president and the chair of the FIU Board of Trustees.

- At FIU, to begin the review process, the FIU employee must complete both:
  - The Report of Outside Activity/Conflict of Interest and
Sponsored Research Subawards and Consulting Agreements

- If a sponsored project requires that FIU enter into a subaward or consulting agreement, before the agreement is executed, the PI must advise DOR, Pre-Award, of any SFI relative to that agreement.

- These disclosures are done by the Investigator completing the Subcontract Agreement/Amendment Request Form or the Consulting Agreement/Amendment Request Form, as applicable, which are available on the DOR website.

- If the SFI arises after the subaward or consulting agreement is executed, the PI shall disclose to DOR, Pre-Award, the SFI as soon as the PI learns of it.
Special Rule for Clinical Research funded by PHS

In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by applicable PHS regulations, FIU must require disclosure of the conflicting interest in each public presentation of the results of the research.
PHS/NIH COI Resources

• Financial Conflict of Interest Tutorial

• COI FAQs for PHS funded research

• NIH Office of Extramural Research Conflict of Interest page
  http://grants.nih.gov/grants/policy/coi/
NSF Funded Projects - COI Requirements

- NSF requires that, for each proposal submitted to NSF, the PI must certify that he/she has appropriately disclosed any significant financial interests related to that proposal.

- For projects funded by the NSF, FIU must inform the NSF’s Office of the General Counsel if FIU is unable to satisfactorily manage an actual or potential COI.

- FIU’s notification that the COI cannot be managed, reduced, or eliminated must be submitted electronically via the NSF FastLane system.
If COI in Research Policy is not followed...

An Investigator’s failure to disclose a SFI as required by the COI in Research policy or to follow any conditions imposed pursuant to the University’s review of such SFI may be grounds for disciplinary action, up to and including termination.
• This education module has focused on disclosures of COI in research.

• Please make sure you also review the education module that addresses disclosure obligations under Florida law.

• If you have any questions regarding COI in research, please direct your questions to:
  • Division of Research, Pre-Award
    11200 S.W. 8th Street, MARC 430
    Miami, Florida 33199
    Telephone: (305) 348-2494