UNIVERSITY OF MIAMI
SPONSORED PROGRAMS POLICIES AND PROCEDURES

Section C: Non-Financial Compliance Issues
Policy C8: Conflict of Interest

PURPOSE:

To establish the University of Miami’s position in regards to the conflicts of interest of academic researchers, research teams and educators.

The increasing involvement of academic researchers, research teams and educators with industry and private entrepreneurial ventures has raised the potential for conflict of interest. These conflicts arise from an individual’s opportunities to benefit financially from the outcome of his/her research or other activities conducted as a University researcher, educator, or as part of a University research team. This policy is designed to promote objectivity in research, scholarly and educational activities funded under external grants, contracts or cooperative agreements. By requiring the review of disclosures of interests made by our investigators (faculty, trainees, students, staff and subcontractors) relating to their institutional responsibilities, the policy establishes standards that provide a reasonable expectation that the design, conduct, and reporting of such activities will be free from bias resulting from individual financial and obligatory conflicts of interest.

The Vice Provost for Research is responsible to the Executive Vice President and Provost for the overall coordination of research at the University. The Vice Provost for Research is the chief administrative officer of the University of Miami Office for Research and has been designated by the Provost to solicit and review disclosures of potential conflicts of interest related to externally funded research, scholarly and educational activities at the University of Miami.

This policy supplements the existing university policy contained in the University of Miami Faculty Manual and other University policies and procedures on this subject. In the event of conflict as it relates to funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements, the provisions of this policy will apply.

DEFINITIONS:

Conflict of interest (COI) means an actual or potential interest that could directly and substantially (as determined by the Vice Provost for Research and/or his/her designee, acting on behalf of the Provost), affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts or cooperative agreements. COIs can be financial (FCOI) or obligatory (OCOI) in nature.

Contractor means an entity providing property or services under contract for the direct benefit or use of an awarding component.

Disclosure of financial interests means an Investigator’s (collectively, an educator, researcher, etc; see below) disclosure of financial interests to the University.
Financial interest means anything of monetary value, whether or not the quantitative value is readily ascertainable.

A. With regard to any publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure or the value of any equity interest in the entity as of the date of disclosure exceeds $600. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

B. With regard to any non-publicly traded entity, a financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds $600, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock options (vested or unvested), or other ownership interest); or

C. With regard to Intellectual property (IP) rights and interests (e.g., patents, copyrights), a financial interest is considered to be present as soon as protection is sought (e.g., filing an invention disclosure, patent application, etc).

The term financial interest does not include the following types of interests: salary, royalties, or other remuneration paid by the University of Miami to the Investigator if the Investigator is currently employed or otherwise appointed by the University of Miami, including intellectual property rights assigned to the University of Miami and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, teaching engagements, service on advisory committees or review panels for, or sponsored by a United States Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Financial conflict of interest (FCOI) means a financial interest that could directly and substantially affect the design, conduct, or reporting of funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

FCOI report means the University’s report of a financial conflict of interest to a funding component.

Governmental agency means any governmental agency that has promulgated regulations or policies requiring investigator financial disclosure or requiring institutional conflict of interest policies relating to award of grants or contracts.

Institutional responsibilities means an Investigator’s professional responsibilities on behalf of the Institution. These may include for example: activities such as research, research consultation, consulting, lecturing, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards, Data and Safety Monitoring Boards, or external advisory boards. Income from, or obligations arising from any outside activity that is related to the Investigator’s institutional responsibilities must be disclosed to the University.

Intellectual Property means the filing of a thought or idea that could be protected.

Investigator means the project director (PD), principal investigator (PI), co-principal investigators, and any other person who could be responsible for the design, conduct, or reporting of

1) research irrespective of funding source, or
2) scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

"Investigator" is used for the purpose of this policy to collectively indicate individuals whose role could be described as an educator, researcher or investigator.

This includes sub-awardees, sub-contractor(s), consultants and "to be appointed" positions as well as any individual whose biographical sketch is included in the proposal or whose name appears in the budget (including subcontract budgets). The Investigator, as referred to within this policy, includes the investigator’s spouse and dependent children. The phrase “team member” is used interchangeably with Investigator.

Manage means taking action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Obligatory interest means a relationship (regardless of compensation) that involves a responsibility or commitment to an external entity, including but not limited to being a founding member of that entity, or holding scientific advisory or governing board membership.

Obligatory conflict of interest (OCOI) means a responsibility or commitment that could directly and substantially affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic "bench," "clinical" or applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term also includes any scholarly or educational activity for which external funding is available through a contract, grant or cooperative agreement.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the funding agency by the University.

Significant financial interest means:
(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related (associated with a common idea or practice) to the Investigator’s institutional responsibilities:
   A. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
   B. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
   C. Intellectual property rights and interests (e.g., patents, copyrights) become SFIs when an individual receives an aggregated income of $5,000 or more from one entity for said rights and interests.
(2) The term significant financial interest does not include the following types of interests: salary, travel, royalties, or other remuneration paid by the University of Miami to the Investigator if the Investigator is currently employed or otherwise appointed by the University of Miami, including intellectual property rights assigned to the University of Miami and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, teaching engagements, service on advisory committees or review panels for or sponsored by a United States Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

(3) For PHS funded Investigators this also includes any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to an Investigator’s institutional responsibilities that the Vice Provost for Research and/or his/her designee determines constitutes an FCOI with the Investigator’s funded research.

POLICY:
This policy is divided into sections to describe the responsibilities of the University Investigator; the Sub-awardee/subcontractor/consultant that is not a member of the University of Miami community; and finally those of the University Vice Provost for Research, and/or his/her designees.

1. Investigator
   Required Training:
   Each Investigator (any University faculty member, staff, or student who could be involved in the design, conduct or reporting of research irrespective of funding source, or in educational activities funded by an external entity) is required to complete conflict of interest training prior to engaging in research or externally-funded educational activities, at least every four years, and immediately when any of the following circumstances apply:
   A. the University revises its COI policies or procedures in any manner that affects the requirements of University Investigators;
   B. an Investigator is new to the University; or
   C. the University finds that a University Investigator is not in compliance with the University’s COI policy or management plan.

Responsibility to Disclose:
A. Financial and Obligatory Interests
   All Investigators who could be involved in sponsored work must disclose annually to the Vice Provost for Research and/or his/her designee their institutional responsibilities and financial and obligatory interests that could be perceived to be related to any of their institutional responsibilities. In addition, the Investigator must list financial and obligatory interests of his/her spouse and dependent children that are related to the Investigators institutional responsibilities.

   Such disclosures must be made, updated, or certified to the Vice Provost for Research and/or his/her designee:
   • at least annually, prior to the close of the calendar year
   • prior to an application, project or contract being submitted for proposed funding
   • prior to expending funds for a new award (grant or contract)
   • upon joining a project/award/contract team engaged in funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements
• if a new financial interest is discovered or acquired (e.g., through activity, purchase, marriage, or inheritance)
• upon transfer to the University of an externally funded award, contract or cooperative agreement from another institution or entity.

During the pendency or the term of an award or contract, Investigators are required to update disclosures within thirty (30) days of discovering or acquiring new financial or obligatory interests (e.g., through activity, purchase, marriage, or inheritance).

B. Reimbursed or sponsored travel:
PHS funded Investigators must also disclose the occurrence of any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities.

The details of this disclosure include:
• the purpose of the trip,
• the identity of the sponsor/organizer,
• the monetary value,
• the destination, and
• the duration.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The Vice Provost for Research and/or his/her designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

During the pendency or the term of an award or contract, investigators are required to update disclosures regarding reimbursed or sponsored travel within thirty (30) days of the occurrence of the travel.

2. Sub-awardees, sub-contractor, and consultant Responsibilities

Responsibility to Comply:
Sub-awardees, sub-contractors, and consultants on sponsored awards, contracts or cooperative agreements are required to comply with all aspects of the PHS FCOI regulations. In instances that the sub-awardee, sub-contractor, or consultant’s organization does not have a federally compliant COI program, they must comply with the University’s COI policies and procedures. Failure to comply with this policy or adhere to a COI Committee management plan may result in termination of participation in the associated project.

Methods of Compliance:
The University (as an awardee Institution) takes reasonable steps to ensure that any subrecipient Investigator complies with the PHS conflict of interest policy by written agreement with the subrecipient with terms that establish whether the FCOI policy of the University or that of the subrecipient will apply to the subrecipient’s Investigators.

A. If the subrecipient’s Investigators must comply with the subrecipient’s FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the Federal Regulation on FCOI, specifically Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for research contracts. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient
Investigators are subject to the University’s FCOI policy for disclosing significant financial interests that are directly related to the subrecipient’s work for the University;

B. Additionally, if the subrecipient’s Investigators must comply with the subrecipient’s FCOI policy, per the agreement referenced above the subrecipient will report all identified FCOI to the Vice Provost for Research and/or his/her designees within twenty (20) days. This time period is required to enable the University to provide timely FCOI reports, as necessary, to the awarding component.

C. Alternatively, if the subrecipient’s Investigators must comply with the University’s COI policy, the agreement referenced above shall specify that the subrecipient must submit to the University of Miami all disclosures of financial and obligatory interests related to the Investigator’s institutional responsibilities within fifteen (15) business days of submission of the grant or contract proposal. Disclosures are to be submitted directly to the Vice Provost for Research and/or his/her designees. This time period is required to enable the University to comply timely with its review, management, and reporting obligations.

3. University Review of Disclosures:

Disclosures of financial and obligatory interests and level of significance will be reviewed by the Vice Provost for Research and/or his/her designees to determine whether an actual or potential COI exists, and to determine what conditions or restrictions, if any, should be imposed by the University to manage or eliminate such COIs. The Vice Provost for Research and/or his/her designees are responsible for assuring that determinations are the result of consistently applied guidelines, including but not limited to, a review of

A. the nature of the personal relationship between the Investigator and the research;
B. a risk/benefit analysis of patients if involved in the research;
C. the specific role (e.g. patient screening and enrollment; data acquisition, analysis and interpretation) of the Investigator and consideration of how that role can affect the outcome of the research; and
D. the expertise of the Investigator and extenuating circumstances as to why he or she should be involved in the research.

An interest will be determined to be a COI if it exceeds the threshold limits put forth by this policy or if it could directly and significantly affect, or be affected by the design, conduct, reporting or outcome of the funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

Management

Management of an identified COI requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report. Examples of conditions or restrictions that might be imposed to manage or eliminate actual or potential conflicts of interest include, but are not limited to:

- Public disclosure of COIs;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in specific portion(s) of the funded research that would be affected by the COI;
- Divestiture or reduction of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.
The Investigator will affirm in writing that he/she agrees to comply with the condition(s) and/or restriction(s) imposed by the Vice Provost for Research and/or his/her designees within ten (10) days of receiving the determination letter or management plan.

Management plans are distributed to all relevant individuals, administrative offices and other units as required by the conditions of the plan including but not limited to the Investigator, the Investigator’s supervisor, the Principal Investigator, Human Subjects Research Office, IACUC, the IP Strategy and Licensing office, General Counsel, and Research Administration.

Investigator compliance with the management plan is subject to monitoring and review by the Office of Research Compliance and/or other University compliance offices, including the Human Subject Research Office.

Appeals
If an Investigator does not agree with the decision of the Vice Provost for Research and/or his/her designees, the Investigator may appeal the decision once to the Vice Provost for Research. If the Investigator remains unsatisfied with the subsequent ruling, he or she can further appeal the determination to the Provost, whose decision will be final. For an appeal to be valid, the Investigator must file each appeal with the Vice Provost for Research and/or his/her designees in writing within 10 business days of receiving the management plan.

Retrospective Review:
Whenever an interest related to funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements is not identified or managed in a timely manner including failure by the Investigator to disclose a financial or obligatory interest, or failure by the University to review or manage an interest, the Vice Provost for Research and/or his/her designee has sixty (60) days to determine if the disclosure constitutes a COI.

If determined to be an FCOI related to PHS funding, or upon learning that an Investigator failed to comply with a prior FCOI management plan for PHS-funded research, the University shall complete a retrospective review of the Investigator’s activities within one hundred and twenty (120) days of the discovery of nondisclosure/ determination of noncompliance in order to determine whether the research or scholarly activity, or any portion thereof, conducted during the time period of noncompliance, was biased in design, conduct, or reporting.

Further, regardless of type of COI or origin of funding, the University has the option to conduct a similar retrospective review in order to determine if the design, conduct, or reporting of the research or scholarly activity was biased.

Depending on the nature of the interest, the Vice Provost for Research and/or his/her designee may determine that additional interim measures are necessary with regard to the Investigator’s participation in the funded research project or scholarly activity until the completion of the Institution’s review.

If bias is found, the University will notify and submit a mitigation report to the awarding component (as required). The mitigation report will include the key elements documented in the retrospective review, a description of the impact of the bias on the research project, and the University’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the PHS funded research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the University will submit FCOI reports annually for the duration of the funded project, including extensions with or without additional funding.
Further, if the NIH determines that one of its funded clinical research projects 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 an FCOI that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

**Enforcement and Sanctions:**
Regardless of funding source, failure to comply with a determination of the Vice Provost for Research and/or his/her designees or failure to comply with this policy will be brought to the attention of the Investigator’s supervisor, Dean, and the Provost. The Provost will have the option of taking appropriate action(s) including but not limited to withdrawal of pending proposals and/or placing a hold on, or terminating, an active award, contract or cooperative agreement. In addition, if required, the University will notify the awarding component of the Investigator’s failure to comply with the determination and/or policy.

**Public Access:**
The University will maintain a website to ensure public accessibility to this policy and information concerning any significant financial interest disclosed to the University that meets the following three criteria:

A. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy;
B. The University determines that the significant financial interest is related to funded research or to scholarly and/or educational activities funded under external grants, contracts or cooperative agreements; and
C. The University determines that the significant financial interest is a FCOI.

The information presented includes the Investigator’s name; the Investigator’s title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest, 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.

This information will be provided on the website prior to the University’s expenditure of any funds under the relevant funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

The University will update the website within sixty (60) days of the University’s receipt or identification of information concerning:

- any additional significant financial interest that was not previously disclosed held by the senior/key personnel for the funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements project, or
- upon the disclosure of a significant financial interest of senior/key personnel new to the funded research project or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

The information will remain publically available for three years from the date on which the information was most recently updated.

**Advising External Funding Entity:**
The Vice Provost for Research and/or his/her designee will be responsible for advising an external funding entity regarding actual or potential conflicts of interest according to the policies/requirements of
the external entity. The University does not disclose information related to potential or actual conflicts of interest unless it is required by the awarding component.

Record Retention:
Records of financial interests, significant financial interests, determinations of the Vice Provost for Research and/or his/her designees, appeals and compliance documents, and documents regarding all actions taken to resolve actual or potential conflicts of interest will be maintained by the Vice Provost for Research and/or his/her designees for at least three years following the submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

Compliance with Federal Regulations:
Any regulations promulgated by a governmental agency on conflict of interests will be incorporated by reference in this policy.

REFERENCES AND RELATED RESOURCES:

University of Miami, Faculty Manual.
University of Miami Policy on Audits, 6.3
The University of Miami Medical Group “Interactions with Health Industry Entities” policy

Office of Research Conflict of Interest webpage located at: http://uresearch.miami.edu/?p=173&s=4

APPROVED:

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