



MEMORANDUM

To: Julio Frenk
University President

From: Linda L. Neider
Chair, Faculty Senate

A handwritten signature in blue ink, appearing to read 'L. Neider', is placed over the 'From:' field.

Date: April 22, 2021

Subject: Faculty Senate Legislation #2020-90(B) – Disclosures Related to Conflict-of-Interest Policy, to be included in the *Faculty Manual*.

The Faculty Senate, at its April 21, 2021 meeting, had no objections to disclosures related to the Conflict-of-Interest Policy to be included in the Ethical Matters Section of the *Faculty Manual*. This policy defines the responsibilities and procedures required to mitigate personal and institutional Conflicts of Interest, Conflicts of Commitment, and Undue Foreign Influence at the university.

The proposal is enclosed for your reference.

This legislation is now forwarded to you for your action.

LLN/rh/va

Enclosure

cc: Jeffrey Duerk, Executive Vice President and Provost
Erin Kobetz, Vice Provost, Research and Scholarship; Professor, MSOM
Laura Kozma, Associate V.P., Research Administration
Blanca Malagon, V.P., Audit and Compliance
JoNel Newman, First Vice Chair, Faculty Senate; Professor, Law
Lory Hayes, Director, Compliance

CAPSULE: #2020-90(B) – Disclosures Related to Conflict-of-Interest Policy, to be included in the *Faculty Manual*.

PRESIDENT'S RESPONSE

APPROVED:  _____ DATE: 5/28/21
(President's Signature)

OFFICE OR INDIVIDUAL TO IMPLEMENT: Jeffrey L. Duerk, Executive VP and Provost

EFFECTIVE DATE OF LEGISLATION: IMMEDIATELY
(pending any additional approval by the Board of Trustees)

NOT APPROVED AND REFERRED TO: _____

REMARKS (IF NOT APPROVED): _____

**CONFLICT OF INTEREST, CONFLICT OF COMMITMENT,
FOREIGN INFLUENCE, AND INSTITUTIONAL CONFLICT OF INTEREST POLICY**

Approval: XXXX, 2021

OWNER: Erin Kobetz, Vice Provost for Research and Scholarship
AREA: Disclosures & Relationship Management
APPLICABILITY: University of Miami System-Wide

1. Purpose:

This policy, as approved by University and UHealth compliance offices, defines the responsibilities and procedures required to mitigate personal and institutional Conflicts of Interest, Conflicts of Commitment, and undue Foreign Influence at the University of Miami (“University”) and UHealth.

A conflict arises when the interests of a Covered Person, or those of the University at large, influences, affects or is affected by the University’s educational, clinical care, and scholarly activities.

2. Scope:

All Covered Persons (University Officials, Faculty members, UHealth employees, Investigators, University administrators and staff; further articulated in the Glossary) are expected to comply with this Policy and any procedures adopted by specific schools or departments pursuant to or in furtherance of this Policy.

3. Policy:

This Policy requires that all Covered Persons, upon employment or contract with the University and at least annually,

- A. disclose their outside interests through the University’s online disclosure system and indicate whether they receive other support from any non-UM entity for scholarly activities regardless of whether it is related to UM scholarly activities, and
- B. disclose their Foreign Affiliations, Foreign Income, monetary and non-monetary Foreign Support for scholarly activities, and whether they have participated in any Outside Scholarly Activities with a Foreign Source.
- C. complete training on Foreign Influence.

Covered Persons who are UHealth employees must comply with additional requirements as listed in the [UHealth](#) section.

Covered Persons who are Investigators must also comply with additional requirements articulated in the [Scholarly Activities](#) section.

The [Glossary](#) defines terms utilized throughout this policy.

4. Procedures

4.1. Disclosures:

- 4.1.1. Covered Persons will disclose through the University’s online disclosure system:
 - their financial interests in and activities with external entities related to their Institutional Responsibilities or with entities that do or propose to do business with the University.

- the financial interests of their spouse and dependent children that are related to the Covered Person's Institutional Responsibilities or with entities that do or propose to do business with the University.
- Update for new interests within 45 calendar days of acquisition.

4.1.2. The Institution will disclose University royalty earnings, gifts, purchases, and non-governmental-sponsored scholarly projects. The offices of Technology Transfer, Advancement, Supply Chain Management, and Research Administration will provide the reports, annually, to Disclosures & Relationship Management (DRM) and/or University Compliance Services (UCS).

4.2. Review of Disclosures

University Committees as defined below will review disclosed interests and their level of significance to determine whether an actual or potential personal Conflict of Interest (COI), Institutional Conflict of Interest (ICOI), Conflict of Commitment (CoC) or Foreign Influence (FI) exists, and to determine what conditions or restrictions should be imposed by the University to manage or eliminate such conflicts and influence.

- The **Purchasing COIC** is responsible for reviewing disclosed interests as conflicts (interest and commitment) regarding the academic and financial activities of the University.
- The **Clinical COIC** is responsible for reviewing disclosed interests as conflicts (interest and commitment) regarding UHealth policies and clinical mission.
- The **Scholarly Activities COIC** is responsible for reviewing disclosed interests as conflicts (COIs and ICOIs and commitment) regarding clinical and basic scholarly activities performed under the auspices of the University. The Scholarly Activities Section contains additional information in regards to the Scholarly Activities COIC.
- The **Board of Trustees' COI Sub-Committee** is responsible for reviewing the disclosures of all trustees and University officers. In addition, the Board reserves the authority to review and approve plans for managing or eliminating ICOIs.
- The **Institutional Conflict Review Committee (ICRC)** is responsible for reviewing any situation in which the financial or fiduciary interests of the University or the personal financial or fiduciary interests of a University Official either affect or to reasonably appear to affect the University's teaching, clinical care mission, or design, conduct, reporting, review or oversight of scholarly activities.
- The University **FI Committee** will review disclosures deemed (using an International Risk Review Matrix) to have a high potential to create undue Foreign Influence in the University community and/or inappropriately influence the activities of a Covered Person at the University. The Matrix considers facets of a disclosure (country, activity type, disclosed entity's military/government affiliation, etc.) and the risk that the disclosure presents to the university. Upon request, Covered Persons will disclose associated contracts to the University and/or funding agency, if applicable.

4.3. Management of disclosures

When the University determines that a COI, ICOI, CoC or FI exists, the University may, in its sole discretion, manage the Covered Person's interests and activities, or implement other measures the University deems reasonably necessary to mitigate the conflicts or influence.

4.3.1. University Administration

Covered Persons who have University duties involving the procurement, exchange, receipt of gifts, or sale of goods, services, or other assets; the negotiation or formation of contracts or other commitments affecting the assets or interests of the University; the handling of confidential or privileged information;

the provision of patient care; the conduct of scholarly activities and the handling of any results or resulting transfer of technology; or the rendition of professional advice to the University must recuse themselves of performing such duties involving a personal interest, or those of their spouse and dependent children.

4.3.2. Business Relationships Including Fiduciary Duties

When a Covered Person or their Family Member has a Financial Interest in a business, the Covered Person may not review, approve, or administratively control contracts or business relationships between the University and that business.

4.3.3. Gifts and Contributions

No gifts or accommodations of any type, including unrestricted grants, may be accepted by Covered Person or a family member on the Covered Person's behalf, if accepting the gift or accommodation would place the Covered Person in a compromising position, interfere in any way with the impartial discharge of their scholarly duties to the University, or adversely affect their integrity or that of the University.

4.3.4. Use of University Assets/personnel for non-University Activities

Misappropriation or unauthorized use of University assets/personnel for scholarly activities in connection with any external activity is prohibited. This Policy includes implying sponsorship or endorsement by the University.

4.3.5. Foreign Influence

The University is deeply committed to supporting international collaboration which is vital to fostering scholarship. To ensure concerns regarding some foreign engagements which includes, but is not limited to, diversion of intellectual property, failure to disclose other support and conflicts of commitment, activity or appointment, Covered Persons are required to disclose affiliations, income, support and scholarship with or from a foreign source or entity.

4.3.6. Activities Related to Teaching and Students

Covered Persons are required to disclose when students are required to purchase works used in the classroom that the Covered Person or their spouse created, authored, or co-authored (e.g., textbook(s), computer software, electronic or digital media) and for which the Covered Person or spouse will receive, or anticipate receiving payment, loan, subscription, advance, deposit of money, service, or anything of value.

Examples of additional conditions or restrictions that might be imposed to manage or eliminate the introduction of bias or undue influence include, but are not limited to:

- Public disclosure;
- Monitoring of Institutional Responsibilities by independent reviewers;
- Modification of Institutional Responsibilities;
- Disqualification from participation in specific portion(s) of the Institutional Responsibilities;
- Divestiture or reduction of an interest or foreign support; or
- Severance of relationships that create actual or potential conflicts.

The Covered Person will affirm in writing that they agree to comply with the condition(s) and/or restriction(s) imposed by the University within the management plan. Management plans will be available to all relevant individuals, administrative offices, and other units as required by the conditions of the plan. A Covered Person's compliance with the management plan is subject to monitoring and review by University compliance offices.

4.4. Appeals

If a Covered Person does not agree with the decision of the University, the Covered Person may appeal the decision to the Vice Provost for Research and Scholarship within 15 calendar days of the decision. If the Covered Person remains unsatisfied with the subsequent ruling, they can further appeal the determination to the Provost. Faculty members may, if dissatisfied with the Provost's resolution, seek review by the Committee on Rank, Salary and Conditions of Employment.

4.5. Enforcement and sanctions

Failure to complete the annual disclosure process shall result in a written notification from the University, to the Covered Person reminding them they must complete their disclosure within ten (10) calendar days.

Failure to disclose following the receipt of a delinquency notification shall result in a further warning from the University, with copies to the Covered Person's supervisor, department chair, and dean, as applicable, indicating the Covered Person must complete their disclosure within ten (10) calendar days.

Failure of a Covered Person to disclose following receipt of a second written warning to make a truthful and complete disclosure will be brought to the attention of the Covered Person's supervisor, dean, UHealth CEO (if applicable), the Provost, and the President. The University may take administrative or disciplinary action against the Covered Person up to and including termination of employment. A faculty member who does not comply with the provisions of this policy may have committed unprofessional conduct and thus may be subject to a complaint to the Committee on Professional Conduct under the provisions of B4.10 of the *Faculty Manual*.

4.6. Record Retention

Records of financial interests, significant financial interests, determinations of the University's reviews, appeals and compliance documents, and documents regarding all actions taken to resolve Conflicts of Interest, Conflicts of Commitment and Foreign Influence will be maintained by the University according to the University of Miami Records retention schedule.

4.7. Compliance with Federal Regulations

Any regulations promulgated by a US governmental agency on conflict of interests will be incorporated by reference in this Policy.

5. UHealth Specific Section

5.1. Permitted and restricted activities

UHealth Covered Person must not engage in Restricted Activities. If a Covered Person is uncertain about whether an outside interest or activity requires approval and/or disclosure, the Covered Person has an obligation to seek approval for and disclose the outside interest or activity.

The UHealth Covered Person may proceed with outside interests or conduct such activities only after receiving approval from their department chair. The ultimate responsibility for obtaining approval for any outside interest or activities rests with the UHealth Covered Person.

UHealth-Permitted Activities: ownership, compensation, personal services, consulting, independent contracting activities, appropriate relationships with health care industry representatives, or other relationships with external entities involved in healthcare delivery or the purchase and/or sale of goods and services from and/or to UHealth that do not interfere with the Covered Person's institutional responsibilities and obligations and complies with this policy.

UHealth- Restricted Activities: Employment, ownership, compensation, personal services, consulting, independent contracting activities, relationships with health care industry representatives, or other relationships with external entities involved in healthcare delivery or the purchase and/or sale of goods and services from and/or to UHealth that interfere with the Covered Person's institutional responsibilities and obligations.

Covered Persons who are UMMG Faculty and UHealth clinical providers are required to submit (through their department Chair) all proposed consulting agreements with health industry entities to the UHealth Compliance Office for review to ensure compliance with the applicable University and UMMG policies prior to the execution and acceptance of the agreement(s). UHealth Compliance will respond in a reasonable timeframe (72 hours) to the faculty member/clinical provider with a notification to the applicable Department Chair or Division Chief.

5.2. Gifts and Contributions

UHealth Covered Persons shall not accept any items of value from UHealth's suppliers, vendors, or business partners that are more than "token" or "nominal" value. Token or nominal value is considered to be \$15 per item, and \$75 in the aggregate. Gifts of cash or cash equivalent items are prohibited regardless of value.

No samples of drugs, medical devices, or any other products may be accepted by Covered Persons.

5.3. Clinical Activities

5.3.1. External Ownership, Compensation or Other Relationships

A UHealth Covered Person shall not be permitted to engage in an ownership, compensation, or employment relationship with an external entity that directly or indirectly involves or requires the employee to engage in marketing and/or promotion of any industry item, service, device, or product.

UHealth Covered Persons and clinical or administrative departments shall not accept compensation in exchange for permitting an external entity or individual to observe visits or procedures that will be reimbursed by a federal healthcare program, a private commercial insurance, and/or a self-pay patient.

5.3.2. Fee-for-Service Arrangements

A UHealth Covered Person shall not be permitted to engage in a fee-for-service arrangement that directly or indirectly involves or requires the marketing and/or promotion of any industry item, service, device, or product.

UHealth Covered Person may provide expert witness services on behalf of plaintiffs suing medical providers who are not located in the state of Florida, and on behalf of medical provider defendants who are located in any state.

A UHealth Covered Person that intends to engage in a fee-for-service arrangement must provide their Department documentation of each service that they intend to perform and explicitly state the anticipated compensation that they shall receive pursuant to a written agreement, which shall not be executed until they receive final approval from their Department chair

A Department or UHealth Covered Person that intends to engage in a contract with an external entity that requires the use of UHealth property (including, but not limited to, facilities, office supplies, and medical or technological equipment or supplies) shall notify the Department Chair prior to the negotiation and execution of a fee-for-service contract, and may not use such property until written approval is obtained prior to the execution of the contract.

5.3.3. Support from Healthcare Industry Entities -

Speaking Engagements- A UHealth Covered Person shall only participate in industry sponsored events that are primarily educational and scientific or medical, including, but not limited to, Continuing Medical Education ("CME") accredited events and/or events that are approved by the Department chair and are in compliance the UMMG Interactions with Health Industry Entities policy.

5.4. Enforcement and Sanctions

Failure to comply with a determination of the University or failure to comply with this Policy will be brought to the attention of the Covered Person's supervisor, dean, and UHealth CEO. Department Chairs and Supervisors are accountable for addressing discipline as directed when violations occur within the Department. A faculty member who does not comply with the provisions of this policy may have committed unprofessional conduct and thus may be subject to a complaint to the Committee on Professional Conduct under the provisions of B4.10 of the *Faculty Manual*.

6. Scholarly Activities Specific section

In regards to scholarly activities conducted under the purview of the University, a personal conflict of interest (COI) or an institutional COI (ICOI) means an actual or potential interest that could directly and substantially, affect, or be affected by, the design, conduct, or reporting of scholarly and/or educational activities. Covered Persons who are Investigators ("Investigators," as defined in the Glossary) must comply with additional requirements under this Policy.

The Vice Provost for Research and Scholarship (VPRS), acting on behalf of the Provost, designates responsibilities (as appropriate) to the Scholarly Activities COIC and the DRM.

6.1. Scholarly Activity Specific Procedures

6.1.1. Required Training for Scholarly Activities:

Covered Persons, who are Investigators, are required to complete COI training prior to engaging in scholarly and/or 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. as required by the University for any reason including if the University finds that a University Investigator is not in compliance with the University's COI policy or management plan.

6.1.2. Disclosures:

In addition to those listed in the Policy, Investigators have additional disclosure requirements:

- If required by the sponsor, disclosures must be submitted prior to an application, project, or contract being submitted for proposed funding.
- Obligatory interests must also be disclosed.

6.1.2.1. Project-specific disclosures

In addition to submission of their disclosures, Investigators must answer project-specific questions:

- prior to expending funds for a new award (grant or contract);
- prior to IRB approval of a human subject research study;
- upon joining a project/award/contract team engaged in funded scholarly activities;
- upon transfer to the University of an externally funded award, contract, or cooperative agreement from another institution or entity.

During the pendency of the term of an award or contract, Investigators are required to update disclosures within 45 calendar days of discovering or acquiring new Financial or Obligatory Interests (*e.g.*, through activity, purchase, marriage, or inheritance) or foreign support.

6.1.2.2. Disclosure of Investigational New Drug Applications (INDs) and Investigational Device Exemptions (IDEs)

An Investigator who is an IND/IDE holder must comply with this Policy when they are a sponsor, investigator, or a sponsor-investigator. In addition, whenever an IND/IDE is held by a University Investigator, the IND/IDE holder's name must be listed in the eProst System for clinical investigations and expanded access treatments (including Emergency Use) conducted at the University of Miami.

When clinical investigations and expanded access treatments (including Emergency Use) are not conducted at or through the University of Miami, for each IND/IDE, Covered Persons will notify the VPRS of

- any new IND/IDE applications prior to submission to the FDA;
- new approvals within five (5) calendar days;
- and provide the associated study information and location(s) where the IND/IDE will be used.

6.1.2.3. Covered Persons who are funded by United States Public Health Service (PHS)-funded agencies, or funded by entities whose policies require that [UM abide by PHS regulation in order to accept their funding](#), must also disclose additional details about 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 additional details of these disclosures 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 US Federal, state, or local government agency, a US Institution of higher education as defined at 20 USC 1001(a), a US academic teaching hospital, a US medical center, or a research institute that is affiliated with a US institution of higher education.

The VPRS will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest with the PHS or PHS-like-funded scholarly activities.

During the pendency or the term of an award or contract, Covered Persons who receive funding from PHS and PHS-like entities are required to update disclosures regarding reimbursed or sponsored travel within **45 calendar days** of the occurrence of the travel.

6.1.2.4. Sub-awardees, Sub-contractor, and Consultant Disclosures

Sub-awardees, sub-contractors, and consultants on NSF or PHS-sponsored awards, contracts, or cooperative agreements are required to comply with all aspects of the NSF or PHS FCOI regulations (as applicable). In instances that the sub-awardee, sub-contractor, or consultant's organization does not have a federally compliant COI program, the University may approve them to comply with the University's COI policies and procedures. Lack of approval by the University or failure to comply with this Policy or adhere to a COI Committee management plan may result in termination of participation in the associated project.

The University (as an awardee Institution) takes reasonable steps to ensure that any subrecipient Investigator complies with the NSF or PHS conflict of interest policy by written agreement with the subrecipient with terms that establish whether the COI 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 COI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the relevant Federal Regulations on COI, specifically Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for scholarly activities contracts for PHS-sponsored awards and the Policy on Conflict of Interest for NSF-sponsored awards. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the University's COI 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 COI policy in support of a PHS-sponsored award, per the agreement referenced above, the subrecipient will report all identified FCOI to the VPRS prior to submission of a proposal for funding.
- 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 responsibilities on the subaward prior to the of submission of the grant or contract proposal. Disclosures are to be submitted directly to the VPRS. This time period is required to enable the University to comply timely with its review, management, and reporting obligations.

6.2. Review of Disclosures

6.2.1. Investigator Disclosures:

The **Scholarly Activities COIC**, designated by the VPRS, will review Investigator disclosures, determine whether the disclosure creates a personal COI or ICOI, and to determine what conditions or restrictions, if any, should be imposed by the University to manage or eliminate such COIs. The Scholarly Activities COIC is 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 scholarly activities;
- B. 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 scholarly activities; and
- C. the expertise of the Investigator and extenuating circumstances as to why they should be involved in the scholarly activities.

An Investigator's interest will be determined to be a COI if it exceeds the threshold limits set forth in this Policy, and if it could directly and significantly affect, or be affected by, the design, conduct, reporting, or outcome of the scholarly and/or educational activities.

6.2.2. Review of Institutional interests related to scholarly activities

When a unit within the University proposes to evaluate an invention in which the University has a financial interest under the terms of a University licensing agreement, and the evaluation is determined by the Institutional Review Board to involve "more than minimal risk" to human subjects, an executive team will gather information for consideration by the full Institutional Conflict Review Committee (ICRC). In assessing and managing potential institutional conflicts of interest involving human subject research (HSR), the ICRC presumes that the HSR should not be conducted at the University unless there are compelling circumstances that justify proceeding with the HSR at the University despite the institutional conflict.

6.3. Management

Management of an identified COI (personal or Institutional) and Investigator CoCs is described in the Policy.

When an Investigator is an executive officer of or has a fiduciary duty to a subcontracting or subawardee entity, they should receive VPRS approval before engaging in or conduct duties for scholarly activities or service projects with that entity.

6.4. Appeals specific to scholarly activities

If an Investigator does not agree with the decision of the Scholarly Activities COIC, the Investigator may appeal the decision to the VPRS within 15 calendar days of the decision. If the Investigator remains unsatisfied with the subsequent ruling, they may appeal the determination to the Provost. Faculty members may, if dissatisfied with the Provost's resolution, seek review by the Committee on Rank, Salary and Conditions of Employment.

6.5. Enforcement and sanctions specific to scholarly activities

In regards to scholarly activities and failure to comply with this Policy, 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. A faculty member who does not comply with the provisions of this policy may have committed unprofessional conduct and thus may be subject to a complaint to the Committee on Professional Conduct under the provisions of B4.10 of the *Faculty Manual*.

6.5.1. Retrospective Review for PHS-funded scholarly activities

Whenever an interest related to sponsored scholarly activities 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 VPRS has sixty **(60) calendar days** of identification of the interest to determine if the disclosure constitutes a COI.

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

Further, regardless of the type of conflict or the 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 scholarly activities were biased.

Depending on the nature of the interest, the VPRS may determine that additional interim measures are necessary with regard to the Investigator's participation in the 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 as required by regulations. Thereafter, and as required by the awarding component, the University will submit FCOI reports **annually** for the duration of the funded project, including extensions with or without additional funding.

Further, if the National Institutes of Health (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 a 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.

6.6. Advising External Entities

6.6.1. Human subject research

Investigators who are participating on human subject research will disclose to participants any relationship to the study (e.g., consulting for the sponsor or for the manufacturer of a drug used in a study), irrespective of receipt of compensation. The method of disclosure of the conflict to study participants is at the purview of the Institutional Review Board.

6.6.2. Funding Entities

The VPRS will be responsible for advising an external funding entity regarding actual or potential scholarly activity-related COIs according to the policies/requirements of the external entity. The University does not disclose information related to potential or actual scholarly activity-related COIs unless it is required by the awarding component.

6.6.3. FDA Reporting Requirements IND and IDE Holders/Sponsors

If the IND/IDE holder/Sponsor does not have an identifiable disclosable financial arrangement to report, a Form FDA 3454 (Certification: Financial Interests and Arrangements of Clinical Investigators) must be completed/collected. If an identifiable disclosable financial arrangement exists, a Form FDA 3455 (Disclosure: Financial Interest and Arrangement of Clinical Investigators) must be completed/collected to disclose the financial arrangement.

Note: if the IND/IDE holder is the Sponsor-Investigator for the clinical investigation/expanded access, only one form is completed/collected. If other Investigators are involved in the clinical investigation/expanded access, the IND/IDE holder/Sponsor can attach a list of all Investigators without a disclosable financial arrangement to Form FDA 3454. However, an individual Form FDA 3455 must be completed/collected by each Investigator in the study reporting a disclosable financial arrangement.

6.6.4. Public Access

The University will maintain a website to ensure public access 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 scholarly activities funded under PHS-funded grants, contracts, or cooperative agreements; AND
- C. The University determines that the significant financial interest is an FCOI.

The information presented includes the Investigator's name; the Investigator's title and role with respect to the scholarly activity; 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 PHS-sponsored scholarly activities.

The University will update the website within sixty (60) calendar 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 PHS-funded scholarly 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 scholarly activity funded under external grants, contracts, or cooperative agreements.

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

6.7. Record Retention specific to scholarly activities

Records of financial interests, significant financial interests, determinations of the VPRS , appeals and compliance documents, and documents regarding all actions taken to resolve actual or potential scholarly activity-related COIs will be maintained by the VPRS for at least three years following the submission final expenditures report of an award or contract, according to the University of Miami Records retention schedule and, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

7. Glossary

Board of Trustee's Conflict of Interest Sub-committee is a sub-committee of the Executive Committee of the Board of Trustees (BOT) responsible for reviewing disclosures by Trustees and key personnel (as designated by the General Counsel) of potentially conflicted matters to determine whether a conflict of interest exists and whether it should be eliminated or managed.

A Conflict of Interest ("COI") is any circumstance in which a Covered Person's personal, professional, financial, or other interests may potentially or actually cause them to diverge from, or may be reasonably perceived as potentially or actually diverging from, unbiased and objective fulfillment of their obligations to the University of Miami and/or UHealth.

Conflict of Commitment means a situation where a Covered Person engages in internal or external activities, either paid or unpaid, that interfere with their obligations and commitments to the University and/or UHealth. Covered Persons should evaluate and arrange their interests in order to avoid compromising their ability to carry out their obligations to the University, and most Conflicts of Commitment should generally be avoided or resolved through the exercise of personal judgment or

discretion. Notwithstanding the above, this Policy prohibits a Covered Person from participation in a foreign talent program or similar-type programs, both paid and unpaid.

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

Covered Person means those individuals subject to the disclosure and other requirements specified in this Policy, which includes but is not limited to:

- University Officials: Trustees, president or president's chief of staff; senior vice president, vice president, associate and assistant vice president, director; provost, vice provost, associate vice provost, and assistant vice provost; dean, vice dean, associate and assistant dean, associate and assistant vice-dean, department chair; medical division chief, medical director, department chair, and vice-chair; athletic director, deputy director; and general counsel.
- All faculty and other academic appointees of the University, including voluntary, full-time and part-time, and visiting scholars
- Graduate students, foreign students, postdoctoral associates, and volunteers
- Administrative positions with independent authority to make purchasing decisions or otherwise bind, negotiate on behalf of, or execute agreements for the University, which include:
 - Employees in any department at a management level; and
 - Exempt (salaried) employees at any level in the following departments: Compliance and Internal Audit, Development, Facilities, Finance, General Counsel, Investments, Research Administration, Office of Technology Transfer, and Procurement.
- Individuals, regardless of level or title, whether internal or external to the University, that serve on University institutional committees with responsibility for oversight of scholarly activities, formulary, or purchasing decisions (*e.g.*, Institutional Review Board, Pharmacy and Therapeutics Committee, Value Analysis Committee); and
- Employee who is a full-time or part-time, exempt or non-exempt employee of UHealth, a clinical provider who performs clinical services at UHealth, an affiliated volunteer who provides services to UHealth, or a full-time or part-time employee of a third party contracted with UHealth to provide temporary staffing services
- Individuals responsible for the design, conduct, or reporting of scholarly activities; this may include individuals that are not employees of the University and who do not have their own COI policy.

Disclosures and Relationship Management (DRM) is the unit within the Office of the Vice Provost for Research and Scholarship (OVPRS) responsible for administering the disclosure system, process for disclosures to the University, and managing personal and institutional conflicts of interest related to scholarly activities.

Family or Family Member for purposes of disclosure within this Policy means the spouse and dependent child of a Covered Person.

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

Fiduciary means a Covered Person who has a legal interest to act in the best interest of an entity or individual.

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 (12) 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). For purposes of this definition, 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 (12) months preceding the disclosure exceeds \$600, or when the Covered Person (or the Covered Person's spouse or dependent children) holds any equity interest in the entity (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 to the Covered Person if the Covered Person 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, as long as the Covered Person does not directly control the investment decisions made in these vehicles; and 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 USC 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, or be affected by, the Covered Person's professional obligations to the University, including the design, conduct, or reporting of scholarly activities.

Financial Support (regardless of amount) means direct or indirect support for a student, postdoc for other visiting scholar to enroll in, train, conduct scholarly activities, or to otherwise visit UM.

Foreign Affiliation means a professional affiliation with a Foreign Source. "Professional affiliations" include, but are not limited to, extra-institutional titles and affiliations, activities, relationships, professional or academic appointments (paid or unpaid), regardless of the effort (full-time, part-time, or voluntary), including but not limited to, a foreign institution of higher education, a foreign public or private entity, the government of another country, or a foreign talent programs (e.g., Thousand Talents Program, National High-End Foreign Expert Recruitment Plan, Yangtze River Scholars).

Foreign Income includes, but is not limited to, income received for any publication, presentation or speaking engagement (such as a conference, symposium or presentation). "Income" also includes, but is not limited to, income that is unrelated to University institutional responsibilities, as well as income for events that took place within the U.S.

Foreign Influence is any circumstance involving a Financial or Obligatory Interest in or with a non-US entity; monetary or non-monetary foreign support for scholarly activities, or any form of Financial Support (as defined above) received from a non-US entity that could influence the activities of a Covered Person at the University.

Governmental Agency means any US government agency that has promulgated regulations or policies requiring a Covered Person's financial disclosure or requiring that an institution maintain conflict of interest policies.

An Institutional Conflict of Interest is any situation in which the financial or fiduciary interests of the University or the personal financial or fiduciary interests of a Covered Person, either affect or to reasonably appear to affect the University's teaching, clinical care mission, or design, conduct, reporting, review, or oversight of scholarly activities.

The Institutional Conflict Review Committee (ICRC) is the committee established to evaluate potential institutional conflict of interest situations, develop, review, and assist with enforcement of ICOI management plans, review information relating to post-approval implementation of management plans, and provide counsel to the Board of Trustees conflicts of interest sub-committee.

Institutional Responsibilities means a Covered Person's professional responsibilities on behalf of the University, such as scholarly activity 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 are related to the Covered Person's Institutional Responsibilities must be disclosed to the University.

Innovations means patentable or un-patentable inventions, discoveries, processes, compositions, research tools, data, ideas, databases, know-how, copyrightable works, and tangible property, including biological organisms, engineering prototypes, drawings, and software created, conceived, or made by Covered Persons within their normal duties (including clinical duties), course of studies, field of research or scholarly expertise or making more than incidental use of University's resources.

Intellectual Property (IP) means patent applications and patents, copyright registrations and renewals, trade secrets and trademarks.

Investigator means a Covered Person who is the project director (PD), principal investigator(s) (PIs), co-investigators, and any other person substantively contributing to the design, conduct, or reporting of

- A. sponsored scholarly activities (funded under external grants, contracts, or cooperative agreements)
- B. other human subject research, or
- C. sponsored scholarly and/or educational activities.

"Investigator" is used for the purpose of this policy to collectively indicate individuals whose role could be described as that of an educator, researcher, or investigator. Where questions exist concerning whether an individual qualifies as an investigator, the decision will be made by the Vice Provost for Research and Scholarship.

Manage means taking action to address a Conflict of Interest, Conflict of Commitment, or Foreign Influence.

Monetary foreign support for scholarly activities means a Foreign Source provided monetary resources that supports University scholarly activities. "Monetary resources" does not include grants, contracts, or gifts awarded/given to UM. "Scholarly activities" includes, but is not limited to, consulting on a research study; serving as a Principal Investigator for another institution; and teaching and/or mentoring graduate students, publications, presentations, and speaking engagements, such as at a conference or symposium.

Non-monetary foreign support for scholarly activities means a Foreign Source provided any non-monetary resources that support University scholarly activities. "Non-monetary resources" includes, but is not limited to, equipment, materials, or personnel provided to You or made available to You for Your scholarly activities. "Non-monetary resources" do not include resources arranged through UM as

Unfunded Agreements (UFAs), such as material transfer agreements and/or data use agreements, library access at another institution generally provided to external academics or faculty members, resources included in the proposal of a funded sponsored award managed through UM.

Obligatory Interest means a relationship (regardless of compensation) that involves a responsibility or commitment to an 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 means a responsibility or commitment that could *directly and substantially* affect, or be affected by, a Covered Person's obligations to the University, such as, but not limited to, the design, conduct, or reporting of scholarly activities.

Outside scholarly activities mean any non-UM scholarly activities. Examples include, but are not limited to, consulting on a research study; serving as a Principal Investigator or investigator for another institution; and teaching and/or mentoring graduate students at an entity, irrespective of whether the scholarly activities took place inside or outside of the United States but does not include guest speaker engagements or collaborations that are included in the proposal of a funded sponsored award managed through UM.

Other support means backing from any non-UM entity for scholarly activities regardless of whether it is related to UM scholarly activities. Other support, sometimes referred to as "current and pending support" or "active and pending support" typically includes all resources, regardless of monetary value, available in support of an individual's scholarly endeavors (e.g. grants not managed through UM, access to external resources such as a database or an app, in-kind contributions, device, drug, compound, software, survey, evaluation, etc.). This does not include any other support that is awarded to or managed by or through UM.

PHS means the United States Public Health Service.

A PHS-like entity is a funding entity that requires the University to apply PHS standards for COI identification, management, and reporting in order to accept their funding.

Related means an interest that involves the same or similar focus (academic discipline, disease or injury, molecular target, drug, or device, digital technologies, and platforms) as some aspect of the Covered Person's Institutional Responsibilities.

Senior/key personnel means the Project Director/Principal Investigator and any other person identified as senior/key personnel in a grant application, progress report, or any other report submitted to a funding or government agency by the University.

Significant Financial Interest means:

1. A financial interest consisting of one or more of the following interests of the Covered Person (and those of the Covered Person's spouse and dependent children) that reasonably appears to be related (associated with a common idea or practice) to the Covered Person'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 (12) 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 or more than 5% ownership interest in a single entity. 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). For purposes of this definition 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 (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Covered Person (or the Covered Person's spouse or dependent children) holds any equity interest in the entity (*e.g.*, stock, stock option, or other ownership interest); or
 - C. Innovations and Intellectual Property rights (including but not limited to patents and copyrights), become significant financial interests 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 to the Covered Person if the Covered Person is currently employed or otherwise appointed by the University, including Innovations and 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 Covered Person does not directly control the investment decisions made in these vehicles; and 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, a US institution of higher education as defined at 20 USC 1001(a), a US academic teaching hospital, a US medical center, or a US research institute that is affiliated with a US institution of higher education.
 3. For PHS and PHS-like-funded Covered Persons this also includes any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Covered Person and not reimbursed to the Covered Person so that the exact monetary value may not be readily available), related to a Covered Person's Institutional Responsibilities that the Vice Provost for Research and Scholarship and/or their designees determines constitutes a financial conflict of interest with the Covered Person's scholarly activities.

A Significant Financial/Fiduciary Interest (Institutional) is a financial interest of the University which includes, but is not limited to the following:

1. Royalties: Institutional COI may be present when the institution has agreements to receive milestone payments and/or royalties from the sales of an investigational product that is the subject of the scholarly activities.
2. Publicly traded equity: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company that is i) the sponsor of scholarly activities at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution.
3. Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is: i) the sponsor of scholarly activities at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution.
4. Gifts from sponsors: When the institution has received substantial gifts (including gifts in kind) from a potential commercial sponsor of scholarly activities or a company that owns or controls products being studied or tested, or an individual affiliated with these companies, the following circumstances should be evaluated:
 - A. Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire institution, it might affect, or reasonably appear to affect, oversight of scholarly activities at the institution;

- B. Whether a gift is held for the express benefit of the college, school, department, institute, or other unit where the scholarly activity is to be conducted; or
 - C. Whether any Covered Person who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed scholarly activity has been involved in solicitation of the gift.
5. Governance/Fiduciary roles: Through technology licensing activities or investments related to such activities, the University has obtained the right to appoint one or more directors to the governing board of any company that is (i) the sponsor of scholarly activities at the University, or (ii) the manufacturer or distributor of a product that is either studied or tested in scholarly activities at or under the auspices of the University, or based at least in part on technology developed here.

University Compliance Services (UCS) is the central University office with the collaboration of the Office of the Secretary of the Board of Trustees, administers the system and processes for disclosures of conflicts by the Trustees, officers, and other key personnel.

8. References and Related Resources:

University of Miami, Faculty Manual.
University of Miami, Policy on Audits, 6.3

University of Miami Medical Group (UMMG) Consulting Policy
UMMG Interactions with Health Industry Entities
UMMG Compliance Metrics Compensation
University of Miami, [Records Retention Schedule](#)
Office of the Vice Provost for Research and Scholarship [website](#)

Public Health Service (PHS) [Code of Federal Regulations 42CFR50, 42CFR94](#)
National Institutes of Health (NIH) [Grants Policy Statement](#)
NIH [Notice Covering Other Support, FCOI, and Foreign Components](#)
NIH [Protecting US Biomedical Intellectual Innovation](#)
NIH [Notice NOT-OD-19-114: Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components](#)

National Science Foundation (NSF) [Proposal & Award Policies & Procedures Guide](#)
NSF [Protecting Research and Facilitating Collaboration](#)
NSF [Personnel Policy on Foreign Government Talent Recruitment Programs](#)

Department of Energy (DOE) [Order 486.1: Foreign Talent Recruitment Programs](#)
Department of Defense (DoD) [Memo: Actions for the Protection of Intellectual Property, Controlled Information, Key Personnel and Critical Technologies](#)

National Aeronautics and Space Administration (NASA) [Class Deviation Implementing NASA Restrictions on Funding Activities with The People's Republic Of China \(PRC\)](#)