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OF MIAMI



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Owner Maria Alcaide:
Professor
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Wide

Conflict of Interest, Conflict of Commitment, Foreign Influence, and Institutional Conflict of Interest Policy

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.

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.

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-University entity for scholarly activities regardless of whether it is related to the University 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 this policy and Foreign Influence.

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.

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.

PROCEDURES

Disclosures

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 30 calendar days of acquisition.
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 & Scholarly Activities Management (DSAM) and/or University Compliance Services (UCS).

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, ICOIs, commitment, and organizational) 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.

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.

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.
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.
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. 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.

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.

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. Irrespective of the nature of the outside interest, management of a Covered Person's COI that involves student activities (e.g. thesis work, internships, etc) will be addressed to ensure the student's right to an unbiased education.

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.

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.

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*.

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.

Compliance with Federal Regulations

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

UHEALTH SPECIFIC SECTION

Permitted and restricted activities

For the purposes of this section, "**Covered Persons**," includes all UMMG Faculty, all Clinical Providers, all UHealth/Miller School of Medicine Deans, and Assistant/Associate Deans, Vice Presidents, Assistant/Associate Vice Presidents, and Vice Provosts, regardless of faculty status.

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 (covered persons who are faculty) or their immediate supervisor (covered persons who are non-faculty). 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.

UHealth Covered Persons who are UMMG Faculty and/or 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 UHealth policies prior to the execution and acceptance of the agreement(s). UHealth Compliance will respond in a reasonable time frame (72 hours) to the faculty member/clinical provider with a notification to the applicable Department Chair or Division Chief.

Gifts and Contributions

1. 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**.

Clinical Activities

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.

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.

A 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 (covered persons who are faculty) or immediate supervisor (covered persons who are non-faculty).

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.

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 with UHealth policies.

Enforcement and Sanctions

1. 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*.

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. An organizational Conflict of Interest means that an interest makes the University unable or appear to be unable to make impartial procurement decisions in the design, conduct, or reporting of scholarly and/or educational activities.

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 DSAM.

Scholarly Activity Specific Procedures

Required Training:

Covered Persons, who are Investigators funded by United States Department of Energy (DOE) or Public Health Service (PHS) agencies, or funded by entities whose policies require that the University abide by

PHS regulation in order to accept their funding, 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. Within thirty (30) days when 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.

Disclosures:

In addition to those listed in the Policy, all 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.
 - Intellectual property utilized in an Investigator's Scholarly Activities must be disclosed.
1. Project-specific disclosures
In addition to submission of their disclosures, Investigators may have to 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 30 calendar days of discovering or acquiring new Financial or Obligatory Interests (e.g., through activity, purchase, marriage, or inheritance) or foreign support.

2. Disclosure of Investigational New Drug Applications (INDs) and Investigational Device Exemptions (IDEs) is required

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.

3. Travel Event Details

Covered Persons who are funded by the DOE, PHS agencies, or funded by entities whose policies require that the University 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 U.S. Federal, state, or local government agency, a U.S. Institution of higher education as defined at 20 USC 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a research institute that is affiliated with a U.S. 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 DOE, PHS or PHS-like-funded scholarly activities.

During the pendency or the term of an award or contract, **Covered Persons** who receive funding from the DOE, PHS and PHS-like entities are required to update disclosures regarding reimbursed or sponsored travel within **30 calendar days** of the occurrence of the travel.

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

Sub-awardees, sub-contractors, and consultants on DOE, NSF or PHS-sponsored awards, contracts, or cooperative agreements are required to comply with all aspects of the DOE, 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 DOE, 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 that its policy complies with the relevant Federal regulations and policies on COI, including:

- for PHS-sponsored awards, 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 and
- for DOE-sponsored awards, the DOE's Interim Conflict of Interest Policy for Financial Assistance, and
- for NSF-sponsored awards, the Proposal and Award Policies and Procedures Guide (PAPPG) Chapter IX - Grantee Standards.

If the subrecipient cannot provide such certification, 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 DOE, NSF, or PHS-sponsored award, the subrecipient will report all identified FCOI to UM's VPRS prior to expenditure of funding.

C. If the subrecipient's Investigators must comply with the University's COI policy, the subrecipient must submit to the UM 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.

Review of Disclosures

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.

Unless approval is granted by the OVPRS, funds may not be expended on a sponsored award prior to the disclosure and review of interests by DSAM, and implementation of a COI Management Plan (if necessary).

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 Institutional Conflict Review Committee (ICRC) or the Scholarly Activities COIC. In assessing and managing potential institutional conflicts of interest involving human subject research (HSR), the Committees presume 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.

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.

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.

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 and/or a **Covered Person's** participation in Scholarly Activities. 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*.

1. Retrospective Review for DOE- and 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 DOE or PHS funding, or upon learning that a Investigator failed to comply with a prior FCOI management plan for DOE- and 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.

Advising External Entities

1. Human subject research
Investigators who are participating on human subject research will disclose to participants any relationship to the study (e.g., any relationship with a non-University entity involved in the study, consulting for the sponsor or for the manufacturer of a drug/device used in a study, intellectual property related to the study), irrespective of receipt of compensation. The method of disclosure of the relationship to study participants is at the purview of the Institutional Review Board.
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.

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.

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 DOE- and 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 DOE- and 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 DOE- and 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.

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.

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 recruitment program or similar-type programs, both paid and unpaid. Foreign talent recruitment programs as defined in this policy (see Definitions) include maligned foreign talent recruitment programs as defined by federal regulations in the Office of Science and Technology Policy Memorandum dated February 14, 2024.

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 and president's chief of staff; senior vice president, vice president, associate and assistant vice president, provost, vice provost, associate vice provost, and assistant vice provost; dean, vice dean, associate and assistant dean, associate and assistant vice-dean.
- 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.
- Employees in key stakeholder departments.
- All UMMG Faculty and all UHealth Clinical Providers, all UHealth/Miller School of Medicine Deans, Assistant/Associate Deans, Vice Presidents, Assistant/Associate Vice Presidents, and Vice Provosts, regardless of faculty status. UHealth includes Miller School of Medicine faculty or employees, 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 Scholarly Activities Management (DSAM) 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**. If required for an incoming award or contract, this definition is expanded to include close family members, or of other members of the covered employee's household.

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

Fiduciary Responsibility means a **Covered Person** who is an executive officer of or 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 (I.P.) 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, or other remuneration paid by the University to the **Covered Person** if the **Covered Person** is currently employed

or otherwise appointed by the University; 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, 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 the University

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.

Foreign Talent Recruitment Program is any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to an individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue, in exchange for that individual –

- A. engaging in the unauthorized transfer of intellectual property, materials, data products, or other nonpublic information owned by a United States entity or developed with a Federal research and development award to the government of a foreign country or an entity based in, funded by, or affiliated with a foreign country regardless of whether that government or entity provided support for the development of the intellectual property, materials, or data products;

- B. being required to recruit trainees or researchers to enroll in such program, position, or activity;
- C. establishing a laboratory or company, accepting a faculty position, or undertaking any other employment or appointment in a foreign country or with an entity based in, funded by, or affiliated with a foreign country if such activities are in violation of the standard terms and conditions of a Federal research and development award;
- D. being unable to terminate the foreign talent recruitment program contract or agreement except in extraordinary circumstances;
- E. through funding or effort related to the foreign talent recruitment program, being limited in the capacity to carry out a research and development award or required to engage in work that would result in substantial overlap or duplication with a Federal research and development award;
- F. being required to apply for and successfully receive funding from the sponsoring foreign government's funding agencies with the sponsoring foreign organization as the recipient;
- G. being required to omit acknowledgment of the recipient institution with which the individual is affiliated, or the Federal research agency sponsoring the research and development award, contrary to the institutional policies or standard terms and conditions of the Federal research and development award;
- H. being required to not disclose to a Federal research agency or employing institution the participation of such individual in such program, position, or activity; or
- I. having a conflict of interest or conflict of commitment contrary to the standard terms and conditions of a Federal research and development award.

UM **Covered Persons** are strictly prohibited from participation in any talent recruitment program that is sponsored by:

- A. a foreign country of concern or an entity based in a foreign country of concern, whether or not directly sponsored by the foreign country of concern;
- B. an academic institution on the list developed under section 1286(c)(8) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232); or
- C. a foreign talent recruitment program on the list developed under section 1286(c)(9) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232).

an academic institution on the list developed under section 1286(c)(8) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232); or a foreign talent recruitment program on the list developed under section 1286(c)(9) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232).

Governmental Agency means any U.S. 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 activities, 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 (I.P.) 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. unsponsored scholarly activities, or
- C. human subject research.

"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 University "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 or made available for scholarly activities. "Non-monetary resources" do not include resources arranged through the University 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 the University.

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.

Organizational Conflict of Interest means a relationship between the University and an external entity compromises the integrity of institutional decision-making. Due to relationships with a parent company, affiliate, or subsidiary organization, the University may be unable or appear to be unable to be impartial in conducting a procurement action involving a related organization.

Outside scholarly activities mean any non-University 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 the University.

Other support means backing from any non-University entity for scholarly activities regardless of whether it is related to University 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 the University, 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 the University.

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.

Scholarly Activities embrace inquiry, research, and creative professional performance, create and/or advance existing knowledge, and broaden the intellectual advancement in areas related to a **Covered Person's** discipline and the University community. Incorporating a **Covered Person's** Institutional

Responsibilities, examples include, but are not limited to teaching, performing research, conducting clinical studies, participation in University service and administration, shaping public policy, editing journals, consulting, and writing or performing.

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, or other remuneration paid by the University to the **Covered Person** if the **Covered Person** is currently employed or otherwise appointed by the University; 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, service on advisory committees or review panels for or sponsored by a United States Federal, state, or local government agency, a U.S. institution of higher education as defined at 20 USC 1001(a), a U.S. academic teaching hospital, a U.S. medical center, or a U.S. research institute that is affiliated with a U.S. institution of higher education.
3. For DOE, 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.

UHealth Compliance (UHC) is the department responsible for identifying and preventing criminal and unethical conduct, creating a centralized source of information on health care regulations, developing and monitoring mechanisms for reporting non-compliance, investigating alleged misconduct, initiating immediate and appropriate corrective action, and reducing UHealth's exposure to civil, criminal and administrative penalties. The department is comprised of the Office of Regulatory Compliance, Educational Initiatives, HIPPA and Privacy Compliance, and Billing Compliance.

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.

1. 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 U.S. 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](#)

DOE [FAL 2022-02 \(12/20/2021\) Interim Conflict of Interest Policy Requirements for Financial Assistance](#)

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) [Frequently Asked Questions \(FAQs\) for Researchers](#)

Approval Signatures

Step Description

Approver

Date

Maria Alcaide: Professor	05/2025
Alberto Caban-Martinez: Professor	05/2025
Lory Hayes: Director, Compliance	04/2025

Applicability

University of Miami, University of Miami Ambulatory Care Surgery, University of Miami Hospital and Clinics, University of Miami Laboratories, University of Miami Medical Group, University of Miami Millers School of Medicine

Standards

No standards are associated with this document

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