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POLICY ON CONFLICT OF INTEREST IN RESEARCH

"The cornerstone for managing conflicts of interest is transparency, and that begins with the Investigator's disclosure of Significant Financial Interests to the Institution." (CITI)

I. INTRODUCTION

The University of Houston is committed to maintaining a research environment that promotes attention to the highest ethical standards for research. This commitment includes compliance with regulatory requirements set forth by the Public Health Service (PHS),^{1,2} the National Science Foundation (NSF), and other regulatory and ethical bodies. It is the responsibility of the University to promote objectivity in research through the establishment of a Conflict of Interest Policy.

A conflict of interest might take various forms, but includes any circumstance where personal, professional, financial, or other private interests of a person or institution compromise or have the potential to compromise the exercise of professional judgment or obligations, or may be perceived as doing so. It is important to note that a conflict of interest depends on the situation and how it can be perceived, not necessarily on the character or the actions of the individual.

Conflicts of interest can arise from the fact that a mission of the University is to promote public good by fostering the transfer of knowledge gained through University research and scholarship to the private sector. Two important means of accomplishing this mission include consulting and the commercialization of technologies derived from University research. It is appropriate that individuals be rewarded for their participation in these activities through consulting fees, sharing in royalties arising from the commercialization of their work, ownership and/or other associations with start-up companies. It is wrong, however, for an individual's actions or decisions, made in the course of his or her University activities, to be guided by considerations of personal financial gain. Such behavior calls into question the professional objectivity and ethics of the individual and reflects negatively on both the Institution and the external sponsor of the research activity. Members of the academic community should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when apparent conflicts of interest arise.

¹ Agencies within the Public Health Service: Administration for Children and Families (ACF), Administration for Community Living/Administration on Aging, Agency for Health Care Research & Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control & Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (HIS), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA), Office of Global Affairs, Office of the Assistant Secretary for Health (OASH), Office of the Assistant Secretary for Preparedness and Response (ASPR)

² Many non-Public Health Service Agencies are now requiring compliance with Public Health Service Conflict of Interest Standards and Thresholds; for example: Alliance for Lupus Research (ALS), American Asthma Foundation (AAF), American Cancer Society (ACS), American Heart Association (AHA), American Lung Association (ALA), Arthritis Foundation (AF), Juvenile Diabetes Research Foundation International (JDRF), Lupus Foundation of America (LFA), Susan G. Komen Breast Cancer Foundation. *These are updated continuously.*

The purpose of this policy is to educate individuals about situations that generate research-related financial conflicts of interest, and to provide means for faculty, staff, students, and the University to identify, manage, reduce, and/or eliminate actual or potential conflicts of interest. Every member of the academic community has an obligation to become familiar with, and abide by, the provisions of this policy.

II. KEY DEFINITIONS

• <u>Investigator</u> – This policy applies to all individuals who meet the definition of Investigator. Specifically:

The project director or principal Investigator, and any other persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research or educational activities funded³ or proposed for funding. In addition, any research team member who indicates a financial interest related to the submission of a human or animal research protocol will be asked to complete a certification.

This policy, therefore, can apply to collaborators, consultants, post-doctoral fellows, graduate students, and others who meet the threshold for responsibility.

At a minimum, all individuals listed as an investigator or key personnel on a research project must file a certification. It is the responsibility of the Principal Investigator (PI) to determine if other research team members meet this threshold based on their role in the research. See Compliance Guidance here.

- Research An activity is considered research if it meets the definition of research provided by the agency funding the project, or any agencies that oversee the project.⁴ If unfunded or not otherwise defined, the following definitions apply:
 - A systematic investigation, including research development, testing and evaluation, designed
 to develop or contribute to generalizable knowledge. Activities which meet this definition
 constitute research for purposes of this policy, whether or not they are conducted or
 supported under a program which is considered research for other purposes.⁵
 - Systematic study directed toward fuller scientific knowledge or understanding of the subject studied. Research is classified as either basic or applied according to the objectives of the sponsoring agency⁶
- <u>Certification/Disclosure Process</u> All individuals who meet the definition of Investigator as defined above must provide certification of their knowledge of and compliance with this policy on an annual

³ For the purpose of this policy, any <u>gifts</u> to a college or department with the intent of funding a research project are treated as a research award

⁴ For example, the U.S. Food and Drug Administration (FDA), in cases of clinical investigations under 21 CFR 46.102 (c)

⁵ 45 CFR 46.102(d): For example, some demonstration and service programs may include research activities.

⁶ https://www.nsf.gov/statistics/fedfunds/glossary/def.htm

basis. The certification process involves either a certification that no significant financial interests exist, or the disclosure of existing significant financial interests to the Institution. In addition to the annual requirement, the acquisition or discovery of new financial interests requires disclosure within 30 days. All disclosures are reviewed by the University of Houston's Conflict of Interest Committee (COIC).

- <u>Significant Financial Interest (SFI)</u> Anything of monetary value, whether the value is readily ascertainable, that 1) is related to the Investigator's professional responsibilities on behalf of the Institution; and 2) belongs to the Investigator or the Investigator's spouse or dependent children. Additional details regarding what constitutes a Significant Financial Interest are specified in Section III.
- Financial Conflict of Interest (FCOI) A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. Similarly, if a significant financial interest could reasonably appear to be affected by the research, or the interest is in entities whose financial interests would reasonably appear to be affected by the research, review and elimination or management of the conflict is required.
- <u>Institutional Responsibilities</u> Investigators' professional responsibilities on behalf of the Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards and Data Safety Monitoring Boards. All duties referred to in the University of Houston Faculty Handbook are considered Institutional Responsibilities.
- <u>Designated Official</u> the individual at the Institution responsible for the solicitation and review of
 disclosures of significant financial interests from each Investigator who is participating in, or is
 planning on participating in, research. The Designated Official for the University of Houston is the Vice
 Chancellor/Vice President for Research and Technology Transfer.

III. CERTIFICATION OF COMPLIANCE

All individuals meeting the definition of Investigator as defined in this policy must certify their knowledge of and compliance with this policy by completing a Conflict of Interest Certification at least annually. Certifications and associated disclosures must also be actively updated:

- At the time of submission for new funding
- If unrelated to proposals for funding, at the time of submission of human or animal protocols if financial relationships related to the research exist
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

⁷ PHS definition

⁸ Also applies to NSF-funded educational activities [NSF Grant Policy Manual, Chapter V, 510]

⁹ NSF definition, also applies to NSF-funded educational activities

All significant financial interests held by investigators and their immediate family members 10 must be disclosed. A Significant Financial Interest (SFI) is a financial interest that falls into one of the following categories and is reasonably related to any of an investigator's institutional duties:

- Remuneration in excess of \$5,000 from a publicly-traded entity¹¹ during the preceding 12 months. 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);
- Equity interest (stock, stock options, or other ownership interest) in a publicly traded company valued in excess of \$5,000 at the time of certification;
- Any combination of the above two items (equity and income) that exceeds \$5,000 during the preceding 12 months;
- Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity, including a start-up company;
- Remuneration that exceeds \$5,000 from a non-publicly traded entity in the past 12 months, or
- Intellectual property rights and interests (e.g. patents and copyrights), upon receipt of such income related to such rights and interests Income related to intellectual property rights in excess of \$5,000 paid by any source other than the Investigator's current Institution¹².

All disclosed significant financial interests that have a potential relationship to the discloser's engagement in research on behalf of the University of Houston are reviewed by the Conflict of Interest Committee (COIC) to determine if these interests conflict, or appear to conflict, with the research.

The following DO NOT require disclosure:

- Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution,
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, or an Institution of higher education within the United States ¹³ as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education,
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

 $^{^{10}}$ Spouse and dependent children

¹¹ A company whose stock is available for purchase by the general public

¹² Unlicensed intellectual property that does not generate income is also excluded from the definition of Significant Financial Interest. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to the regulation

¹³ Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country as detailed here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html

- Income from service on advisory committees or review panels for a federal, state or local government
 agency, or Institution of higher education within the United States ¹⁴ as defined at 20 U.S.C. 1001(a),
 an academic teaching hospital, a medical center, or a research institute that is affiliated with an
 Institution of higher education, or
- Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights

A disclosure MUST include:

- The investigator's current or pending relationship with the outside enterprise or entity in which a significant financial interest exists;
- The relationship of the research¹⁵ to the enterprise or entity,
- The means by which the investigator proposes to address actual or potential conflicts of interest that arise from his/her (or immediate family members) dual University and enterprise or entity roles, and
- The dollar amount of the financial interest in specified ranges.

Common sense must prevail in the interpretation of these provisions. That is, if a reasonable, disinterested person would question the relationship, it should be disclosed and approval sought for the proposed arrangement.

All investigator certifications and associated disclosures are submitted through and maintained within the university's Integrated Compliance Online Network (ICON).

Certifications with disclosures meeting threshold require additional online acknowledgment as follows:

Primary Appointment	Required Signatory if Significant Financial Interest is Disclosed
Tenure track academic faculty appointments	Department Chair
Non-tenure track research faculty appointments	Department Chair
Staff & students employed by an academic department or college	Department Chair

¹⁴ Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country as detailed here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-160.html

¹⁵ or NSF-funded educational activity

Staff & students employed by a Division of Research Center	Department Chair	
Tenure track academic faculty appointments affiliated with a Division of Research Center	Department Chair	
Non-tenure track research faculty appointments with a Division of Research Center	Center Director	
Department Chair	College Dean	
Division of Research Center Directors	Department Chair	
College Dean	Provost	
Provost, VP for Research	President Department Chair (if applicable)	
President	Board of Regents	
Exceptions:		
 College of Social Work College of Architecture College of Law College of Hotel/Restaurant Mgmt College of Optometry College of Nursing Academic Affairs (without department/college affiliation) College of Business (Small Business Development Center only) 	Assoc. Dean for Research Assoc. Dean Provost Sr. Assoc. Dean for Faculty	

Those required to acknowledge the Disclosure are encouraged to provide input with regard to additional factual information, concerns, or any conditions or restrictions that might be imposed by the Institution to manage, reduce, or eliminate such conflict of interest. This information will be made available to the COIC for consideration. The Division of Research reserves the discretion to add additional acknowledgers as deemed appropriate.

TRAVEL

With some exceptions, PHS-funded investigators must disclose reimbursed or sponsored travel paid for by a third-party entity, including non-profit organizations. Disclosure is *not* required for travel sponsored by or reimbursed by a government agency, a U.S. Institution of higher education or a research institute affiliated with such, a U.S. medical center, or a U.S. academic teaching hospital. When a travel request

submitted through Concur indicates that an employee's travel is sponsored or reimbursed by a third party and the traveler is listed on a PHS award, the Conflict of Interest (COI) office in the Division of Research will receive an automated notification to review the Travel Request. *This does not slow down the approval process as the COI office is not involved in approving the Travel Request.* The COI Office will notify the traveler if further disclosure of the travel and reimbursement information is required.

Travel disclosures must include, at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The COIC will determine if further information is required, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with PHS-funded research.

PROCUREMENT

In accordance with Texas Government Code 2261.252 and University policy, all institutional employees who are involved in procurement or contract management must disclose if they plan to purchase, or recommend or approve the purchase of, goods or services for the University of Houston from an entity with which they or a family member have a direct or indirect financial or other interest. In cases where a financial interest disclosed to the COIC may lead to the procurement of goods or services for the university (including university research), the University of Houston Division of Administration and Finance will be notified and the disclosure will be forwarded for their review; this review may result in additional management requirements. For questions regarding Texas Government Code 2261.252, please contact the Division of Administration and Finance.

IV. DISCLOSURE REVIEW PROCESS

All disclosures indicating a significant financial interest will be reviewed by the University of Houston's Conflict of Interest Committee, who shall advise the Vice Chancellor/Vice President for Research and Technology Transfer. This review will take into consideration any comments or concerns provided by the signatory.

An actual or potential conflict of interest exists when the Committee reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of research¹⁷ conducted on behalf of the University of Houston. Additional information may be required by the Committee to make this determination.

¹⁶ Family members include the following relatives of the employee: child, parent, spouse, sister, brother, grandchild, grandparent, mother-in-law, father-in-law, son-in-law, daughter-in-law, stepson, stepdaughter, stepmother, stepfather, brother-in-law, sister-in-law, spouse's grandparent, spouse's grandchild, grandchild's spouse, or the spouse of a grandparent.

¹⁷ or NSF-funded educational activities

The policy does not apply to **Phase I** Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) applications/awards. However as the policy does apply to **Phase II** SBIR/STTR applications and awards, it is highly recommended that such interests are discussed with the COI office as a best practice, to ensure minimal delays in progressing to Phase II awards and beyond.

MANAGEMENT PLANS

If it is determined that a conflict exists, a final written agreement to manage the conflict is established by the COIC¹⁸. The investigator is required to accept the plan within the ICON system. A specific individual¹⁹ is assigned to monitor adherence to this plan and report to the COIC on a routine basis until the conflict is established within ICON to no longer exist.

Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate actual or potential conflicts of interest can include, but are not limited to:

- Public disclosure of the conflict in publications and presentations
- Disclosure to human subjects participating in the research²⁰
- Disclosure to other research team members
- Appointment of an independent third party to monitor the research
- Modification of the research plan, with approval by the sponsor
- Change of personnel or personnel roles so that the individual in conflict does not participate in the part of the research that could be affected
- Reducing or eliminating the financial interest (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts

The institution may also request active monitoring of relationships that are determined not to represent direct and significant conflicts of interest if there is a reasonable potential for a conflict to develop in the future, based on the direction of the research and/or the relationship with the financial interest.

Departments, Colleges, and Center Directors are responsible for ensuring that required management plans are carried out and monitored until the completion of the research. All parties responsible for ensuring compliance with the management plan, including the monitor, will receive notification of the plan as follows:

¹⁸ As delegated by the Institutional Official

¹⁹ The assigned monitor is, by default, the signatory on the disclosure unless otherwise delegated.

²⁰ The U.S. Food and Drug Administration (FDA), in 21 CFR 54, sets forth additional regulatory requirements for financial disclosures by clinical investigators. If a University of Houston investigator holds the IND or IDE for FDA-regulated research, they are considered sponsor-investigators and are responsible for collecting and maintaining financial disclosures and related management plans. Please contact the COIC at COI@Central.uh.edu if you are a sponsor-investigator.

Position	Parties Copied on Management Plan (in addition to the Signatory, plan monitor, and VP for Research/Tech Transfer)
Tenure track academic faculty appointments	College Dean
Non-tenure track research faculty appointments	College Dean
Staff & students employed by an academic department or college	College Dean
Staff & students employed by a Division of Research (DOR) Center	Center Director
Tenure track academic faculty appointments affiliated with a DOR Center	College Dean
Non-tenure track research faculty appointments with a DOR Center	N/A
Department Chair	Provost
Division of Research Center Directors	N/A
College Dean	N/A
Provost, VP for Research	College Dean (if applicable)
President	N/A
Exceptions:	
 College of Social Work College of Architecture College of Law College of Hotel/Restaurant Mgmt College of Optometry 	College Dean College Dean College Dean College Dean College Dean

College of Nursing

- Academic Affairs (without department/college affiliation)

College of Business (Small Business Development Center only)

College Dean

College Dean

Should an investigator wish to appeal a decision made by the COIC, he or she may present the appeal in writing to the Committee through the following email address: coi@central.uh.edu. The Institutional Official will be made aware of all appeals.

V. TRAINING

All individuals meeting the definition of Investigator in Section II must take an Institutionally-recognized FCOI training course before utilizing research funds and at least once every four years²¹. The University of Houston recognizes the FCOI modules 1 and 2 provided through the Collaborative Institutional Training Initiative (CITI), of which UH is a member. Additional training may be required more often under certain circumstances (e.g., failure to disclose significant financial interests, noncompliance with approved management plan).

VI. RESPONSIBILITIES

A. Institution

1. Designated Official (DO)

The University of Houston Designated Official, for purposes of this policy, is the Vice Chancellor/Vice President for Research and Technology Transfer. The Designated Official is responsible for the solicitation and review of disclosures of significant financial interests from each Investigator at the Institution. The DO has delegated the solicitation/review responsibility to the University of Houston's Conflict of Interest Committee (COIC). The DO is provided all plans for the management of financial conflicts of interest, and works closely with the Committee to provide input as necessary.

2. The Conflict of Interest Committee (COIC)

The University of Houston's Conflict of Interest Committee reports to the Vice Chancellor/Vice President for Research and Technology Transfer. The COIC is comprised of a minimum of 5 COIC members, which includes a Chairperson. As necessary, ex-officio members²² (including regular exofficio representation from UH General Counsel) and a non-affiliated member²³ may be included. Members will be chosen to best represent the expertise and interests of the research being conducted at the University of Houston. COIC members will meet on a monthly basis as needed

²¹ Once the initial training has been completed, CITI offers a refresher course for every subsequent 4 years.

²² Ex-Officio (non-voting) member: An ex-officio member will be chosen to provide additional information and assistance relevant to the COIC dealings, but will not be a voting member.

²³ Non-Affiliated Member: A non-affiliated member with no direct family or University ties.

to review the disclosures and annual certifications that have been submitted through the ICON system to the Division of Research.

The COIC will determine²⁴ whether an Investigator's submitted SFI could directly and significantly affect the research or is in an entity whose financial interest could be affected by the research. If it is determined that either of these conditions is valid, a Financial Conflict of Interest exists. In the case of a Financial Conflict of Interest and prior to the expenditure of any research funds, the COIC will work with the Investigator, Chair, Dean, and DO to develop a plan to manage or eliminate the conflict, and to ensure to the extent possible that the research is free of bias.

COIC members will serve for a term of three years, at which time membership services and representation of the University's research interests will be reviewed. Members can serve consecutive terms with the concurrence of the DO. The COIC Chair and/or DO reserves the right to replace any committee member for non-performance or reasons related to ethical concerns.

3. Additional Division of Research (DOR) Responsibilities

- Maintenance of an up-to-date, written, enforced policy on research FCOI, made available through the publicly accessible University of Houston Division of Research website.
- Notification to Investigators of new regulations and revised Institutional policy/Investigator responsibilities.
- Reporting all required information regarding Financial Conflicts of Interest to federal sponsors.
- Making information regarding FCOIs of senior/key personnel on PHS funded projects publicly available.
- Maintenance/retention of all required FCOI records per funding agency requirements.

B. <u>Investigator</u>

- Being familiar with and abiding by federal regulations and UH Policy regarding FCOI.
- Ensuring that FCOI training is complete prior to utilizing research funds and at least once every four years, as outlined in section V.
- Filing an FCOI Certification and disclosure (if appropriate) to the Institution annually and within 30 days of discovering or acquiring a new significant financial interest.
- Confirming agreement to and complying with any management plan issued by the Institution; retaining documentation that demonstrates compliance with the management plan, such as but not limited to: notices to journal editors or conference audiences, consent forms from human subjects research, and notices to laboratory personnel.

C. Colleges, Departments, and Center Directors

²⁴ Within 60 days for PHS-funded research.

- Colleges, Departments, and Center Directors are responsible for ensuring that investigators submit annual certifications and disclosures.
- Ensuring that the assigned plan monitor adheres to the monitor reporting timeline as determined by the COIC.
- As indicated in Section III, signatories are encouraged to provide input with regard to additional
 factual information, concerns, or any conditions or restrictions that might be imposed by the
 Institution to manage, reduce, or eliminate such conflict of interest. Acknowledgers will also be
 actively involved in the final monitoring of plans to manage or eliminate conflicts.
- Departments, Colleges, and Center Directors are responsible for ensuring that required management plans are carried out and monitored until the completion of the research.

VII. AWARDEES AND SUBRECIPIENTS

When the University of Houston is the primary awardee of a collaborative PHS- or NSF-funded project, it must assure that the financial interests of all subrecipients are reviewed and eliminated or managed properly. During the proposal stage and during the negotiation of a subaward, all subrecipients/potential subrecipients of PHS funding will be required to certify the following in writing via a Letter of Compliance:

- The subrecipient Institution has a policy in place to review and manage Significant Financial Conflicts of Interest that meets regulatory requirements.
- The subrecipient's policy applies to the subawarded portion of the research project, and
- The subrecipient must agree that the identification of and management plan of any FCOI identified will be submitted to the awardee Institution for required reporting purposes.

If the subawardee Institution does <u>not</u> have a compliant FCOI program in place, the agreement must indicate that the subrecipient will follow UH FCOI policy, including the pre-award and annual submission of a Certification (and disclosure, if applicable) to the UH COIC within 30 days of the submission of the proposal.

VIII. REPORTING

The Division of Research is responsible for reporting Financial Conflicts of Interest to funding agencies, as applicable:

Public Health Service (PHS)-Funded Projects

Initial Report

Prior to the expenditure of funds under a PHS-funded research project, the University of Houston
must report any Investigator Significant Financial Interests that are determined by the COIC, or a
subrecipient Institution, to constitute a Financial Conflict of Interest.

Interim Reports

- The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award.
- A FCOI report is required in cases of noncompliance (when an Investigator does not disclose a
 previously existing Significant Financial Interest in a timely fashion or the Institution fails to review a
 previously existing Significant Financial Interest during an ongoing NIH-funded project).

Annual Reports

For any Financial Conflict of Interest previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports must specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. Annual FCOI reports must be submitted to the NIH for the duration of the project period (including extensions with or without funds) at the same time the Institution is required to submit the annual progress report, but through an alternative mechanism.

National Science Foundation (NSF)-Funded Projects

The University of Houston must notify NSF's Office of the General Counsel if it determines that it is unable to manage a Conflict of Interest related to an NSF-funded project satisfactorily. If the University of Houston determines a financial conflict with NSF research to be unmanageable (i.e. imposing conditions or restrictions would be either ineffective or inequitable, and the potential negative impacts that may arise from a significant financial interest are outweighed by the interests of scientific progress, technology transfer, or the public health and welfare), the NSF Office of the General Counsel will be notified electronically. UH and awardees will cooperate with the OGC's review of the institutional conflict of interest policy, actions taken by the institution with respect to the unmanageable conflict, and NSF requests for confirmation that proposed actions have been accomplished.

Other Funding Agencies

The University of Houston will make other required FCOI reports based on applicable funding agency requirements.

IX. FCOI RECORD RETENTION

The Division of Research is responsible for the maintenance and retention of all financial disclosure documentation and of all actions taken to resolve conflicts of interest for at least three years beyond the date of submission of the final expenditures report of the grant to which they relate, or until the resolution of any funding agency action involving those records, whichever is longer. Additional retention might be required under 45 CFR 74.53(b) and 92.42 (b) for different situations.

X. NONCOMPLIANCE

Failure of any investigator to comply with this policy shall constitute grounds for disciplinary action. Disciplinary action is based upon a reasonable investigation of the noncompliance and is consistent with the severity of the violation. A range of examples includes, but is not limited to, the requirement for additional training/monitoring for minor violations up to the imposition of restrictions on an academic staff member's participation in sponsored research for severe or continuing violations.

Additional PHS Requirements

- If an investigator fails to disclose a SFI in a timely manner or if for any reason the Institution fails to review a SFI, the Institution must, within 60 days, determine whether the SFI is related to the research, and whether it rises to the level of a FCOI. If found to be an FCOI, a management plan, even if interim, must be implemented. A FCOI report must be made to PHS at this time.
- In addition, where it is discovered that an the University of Houston has failed to manage a FCOI or where a researcher has failed to comply with a management plan, the Institution must, within 120 days, complete a retrospective review of research to determine whether the research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research. If bias is identified, a mitigation report must be developed that outlines a plan of action to eliminate or mitigate the effect of the bias. The results of that determination and the mitigation report must be submitted to PHS.

XI. PUBLIC ACCESSIBILITY

The Institution is required to make its policy on Financial Conflict of Interest publicly accessible via its website. In addition, responses to public information requests for information concerning Significant Financial Interests must be disclosed within five business days in writing. Disclosures must meet the following criteria:

- The significant financial interest was disclosed and is still held by the senior/key personnel as related to the PHS-funded project,
- The Institution determines that the Significant Financial Interest is related to the PHS-funded research,
- The Institution determines that the Significant Financial Interest is a Financial Conflict of Interest.

The information that must be disclosed includes the following:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the Significant Financial Interest is held;
- Nature of the Significant Financial Interest; and

Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000) or a statement that the interest is one for which the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Written Requests for information may be made through:

- UH's public-facing Conflict of Interest website: http://www.uh.edu/research/compliance/coi/contact-us/
- Via email at coi@central.uh.edu.

XII. RELATED RESOURCES

Department of Health and Human Services Code of Federal Regulations:

42 CFR Part 50; 45 CFR Part 94

21 CFR Part 54

Conflict of Interest FAQs

National Science Foundation Award and Administration Guide. Chapter IV

University of Houston Manual of Administrative Policies and Procedures (MAPP 08.01.01)

University of Houston System Administrative Memorandum (SAM 01.G.01)

UH Division of Administration and Finance Travel Request

UH Faculty Handbook

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01/2016

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