

Introduction

Oklahoma State University Center for Health Sciences (“OSU-CHS” or “University”) maintains uniform policies and standards for identifying, and removing, actual Conflicts of Interest and has adopted policies and procedures for managing situations that could give rise to potential or perceived Conflicts of Interest. In determining whether an actual, potential, or perceived Conflict of Interest exists in a given situation, the University will consider the specific details of the situation and make a determination based on the totality of the circumstances. The University believes that clear guidelines and principles for reporting and managing actual, potential, and perceived Conflicts of Interest will assist our faculty, staff, and students in maintaining the highest level of integrity in their endeavors.

Scope

This Policy applies to all Members of the OSU-CHS community who are in a position to influence or commit OSU-CHS resources. Members who are required to submit a Conflict of Interest Questionnaire include: Senior Management (Vice President, Assistant Vice President, Dean, Department Chair, Director, etc.); tenured and tenure-track faculty; Research (anyone involved in conduct, oversight or administration of research in any way); Clinicians (e.g. DO, MD, PharmD, NP, PA, RN, Supervisors); Supervisors; Individuals who make purchasing decisions (e.g. Procard holders, vendor selection committee, departmental buyers); Committee Membership on university committees, such as: Institutional Review Board, Compliance Committee, Scientific Review Committee, IACUC, IBC, CHRUC, CQI, Policy Committee. OSU-CHS reserves the right to require additional Members to submit a Conflict of Interest Questionnaire as it deems reasonably necessary to avoid an actual, potential or perceived Conflict of Interest.

Policy Statement

An actual Conflict of Interest arises in a situation where there is a divergence between an individual’s private interests and his or her professional obligations to CHS, CHS employees, medical staff, patients, or others within the OSU system such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal gain, financial or otherwise. In addition to situations that clearly give rise to an actual Conflict of Interest, individuals are cautioned also to consider gray areas that might create the perception of or the potential for a Conflict of Interest. Perceived or potential Conflicts of Interest can be said to exist in situations where an individual member of the University community (Member), a member of the individual’s family (Family), or a close personal relation (Close Relation) has financial interests, personal relationships, or professional associations with an individual, individuals, or outside organization, such that his or her activities within the University could appear to be influenced by that interest or relationship.

All Members of the University community are committed to identifying and avoiding situations and activities that constitute a Conflict of Interest in the execution of their duties for the University. Furthermore, activities, situations, and relationships that might create the perception of or potential for

a Conflict of Interest must be identified and managed appropriately. In every instance, the University reserves the right to make a determination in light of its best interest.

On no less than an annual basis, all Members who are subject to the Conflict of Interest Questionnaire, whether they are engaged in activities that might create the perception of or potential for a Conflict of Interest or not, are required to submit a Conflict of Interest questionnaire to the Conflict of Interest Review Committee.

Members are further charged with the responsibility of accurate and prompt disclosure to the Reviewer within *15 calendar days* of: (1) a change in status of an existing actual, perceived, or potential Conflict of Interest; and (2) the identification of a new actual, perceived, or potential Conflict of Interest.

Definitions

Conflict of Interest: any situation in which any action or activity of an individual could reasonably be expected to affect his or her independence of judgment with respect to the University's business. A Conflict of Interest arises when there is a divergence between an individual's private interests and his or her professional obligations to CHS, CHS employees, medical staff, patients, or others within the OSU system such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A Conflict of Interest depends on the situation and not on the character of the individual.

University Responsibilities: Professional responsibilities on behalf of the CHS which may include activities such as patient care; clinical activities; teaching; research; administrative or service activities; institutional committee memberships; service on panels such as Institutional Review Boards, Scientific Review Committees, Institutional Animal Care and Use Committees, Internal Data and Safety Monitoring Boards; and/or other duties as specified in your job description and/or employment agreement.

Financial interest: Individual has directly or indirectly, through business, investment, Related Person or family, any of the following:

- (a) An ownership or investment interest in any entity with which the University has a transaction or business arrangement; or
- (b) A compensation arrangement with an organization or entity or individual with which the University has a transaction or business arrangement; or
- (c) An existing or potential ownership or investment interest in or compensation arrangement with, any entity or individual with which the University is negotiating a transaction or business arrangement; or
- (d) a holding by an individual of interest in any outside entity from which the University secures goods or services or which is a competitor of the University

A financial interest is not necessarily a Conflict of Interest. That is to be determined by the appropriate committee that decides if a Conflict of Interest exists.

Compensation includes direct and indirect remuneration as well as anything of monetary value (cash or a cash equivalent, in-kind items or services, gifts, favors, stock, stock options or any other ownership interest, dividend, profit or other return on investment), whether or not the value is readily ascertainable. Any payment for services not otherwise identified as salary; ownership/equity interest, including group purchasing organizations

Honorarium: is any payment, which may take the form of a fee or any other compensation, made to a covered person in consideration for a service performed that is not part of his or her official duties. Such service includes, but is not limited to, delivering a speech, writing, or publishing an article, or participating in any public or private conference, convention, meeting, or similar event. Honorarium shall also include expenses incurred for travel, lodging, and meals related to the service performed.

Intellectual Property: inventions, discoveries, patents, patent applications, scientific or technological developments, improvements, trade secrets, trade and service marks, and know-how, regardless of whether the same is subject to protection under patent, trademark, or other laws, but the term does not apply to copyrightable works falling under the purview of OSU CHS Policy 1-70201 for which patent protection is not sought. (OSU CHS IP policy 1-70202)

Investigator: The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

Remuneration: includes salary and any payment for services not otherwise identified as salary including, but not limited to consulting fees, honoraria, and paid authorship.

Significant Financial Interest: means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). However, note that the term "Significant Financial Interest" does **NOT** include:

- (1) Salary, royalties, or other remuneration from the OSU-CHS;
- (2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (3) Income from service on advisory committees or review panels for public or nonprofit entities;
- (4) An equity interest that when aggregated for the disclosing person and his or her spouse and dependent children, meets both of the following tests:

- i. Does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and,
 - ii. Does not represent more than a five percent ownership interest in any single entity;
- (5) Salary, royalties or other payments that when aggregated for the disclosing person and his or her spouse and dependent children over the next twelve months, are not expected to exceed \$5,000.

Conflict of Interest Categories

Situations and activities may be grouped into one of three categories under this Conflict of Interest Policy:

1. Category A: Not Significant and Generally Permissible Activities

Situations where any Financial Interest held by a Member, Member's Family, or Member's Close Relation does not indicate a Significant Financial Interest *and* where the situation suggests no actual, potential, or perceived Conflict of Interest. These situations may continue without special safeguards or oversight.

2. Category B: Potential or Perceived Conflicts of Interest

Activities which represent Potential or Perceived Conflicts of Interest would be permitted to go forward after disclosure, but only in accordance with a Management Plan that has been approved by the Conflict of Interest Review Committee and OSU-CHS.

3. Category C: Actual Conflicts of Interest

Activities which represent *actual* Conflicts of Interest, and which may be permitted to go forward after disclosure only with an appropriate Management Plan to *eliminate* the conflict, safeguard against prejudice toward University activities, and provide continuing oversight.

Responsibilities

Responsibilities of Department and Unit Heads

It is a responsibility of Department and Unit Heads to ensure that Members are familiar with University policies and procedures relative to Conflict of Interest. Specifically, Department and Unit Heads are charged with the following:

1. Educate Members about OSU-CHS Conflict of Interest Policy.

2. Advise Members with respect to existing and proposed relationships and activities so that they may seek to avoid an actual Conflict of Interest.
3. Work with the Reviewer, Member, and/or the Conflict of Interest Review Committee (COIRC) to develop and implement a Management Plan for any conflicts.
4. Monitor Member compliance with COIRC approved conflict Management Plans as required.

Responsibilities of Reviewer

The Reviewer shall be the Director of Compliance at OSU-CHS, with input and assistance from a designated representative from the Department of Research. It is the responsibility of the Reviewer to identify any actual, perceived, or potential Conflicts of Interest in a Member's disclosure and to report such conflicts to the COIRC along with a Member's proposed Management Plan.

1. All disclosures received by the Reviewer shall be evaluated by the Reviewer for full and accurate information. In the case of an incomplete disclosure, the Reviewer shall communicate with the disclosing Member within *15 calendar days* to request the necessary additional information from the Member.
2. Disclosures identified by Reviewer and confirmed by the COIRC as being *below* the threshold for Significant Financial Interest and which represent *no* Conflict of Interest (Category A) will be allowed to proceed without special safeguards or oversight, i.e., no Management Plan will be needed. The Reviewer must submit these Category A disclosures to the Chair of the COIRC and inform the Member that the proposed activity will be permitted without management or oversight.
3. Disclosures identified by Reviewer as having *potential* or *perceived* Conflicts of Interest (Category B) will be forwarded to the COIRC. These Category B disclosures will be forwarded, along with a proposed Management Plan, to the COIRC for approval. Category B disclosures may be reviewed and related Management Plans may be approved on an expedited basis by the Chair of the COIRC or designee upon request of Reviewer.
4. Disclosures identified by Reviewer as having *actual* Conflicts of Interest (Category C) will be forwarded, along with a proposed Management Plan, to the full COIRC for approval.
5. When the Reviewer determines that a disclosure contains Category B and/or Category C disclosures, the Reviewer will communicate this determination in writing to the Member and assist the Member, if necessary, in developing a proposed Management plan to submit to the COIRC.

Responsibilities of the COIRC

The Conflict of Interest Review Committee (COIRC) is dedicated to properly identifying actual, potential, and perceived Conflicts of Interest at the University and to ensuring the proper management of such Conflicts of Interest. The COIRC provides oversight for Conflict of Interest training and education, recommends amendments to this Conflict of Interest Policy to the OSU-CHS Policy Committee, and reviews those Conflict of Interest disclosures that suggest an actual, potential, or perceived Conflict of Interest (as initially recognized by the Reviewer). If a Conflict of Interest situation arises that requires a Management Plan, the COIRC works in cooperation with the Reviewer, and the Member as needed, to approve an appropriate Management Plan.

COIRC Membership

The COIRC shall consist of 4 voting members: Chief Operating Officer (COIRC Chair), Vice President of Administration and Finance, Provost and Assistant Vice President of Budget and Finance; and one ad-hoc non-voting member: OSU-CHS Staff Attorney. Representatives from the Finance, Human Resources, and the Vice President for Research's Office will serve as ex officio non-voting COIRC members. When a voting member of the COIRC is under Conflict of Interest review, the President of the University will take the voting member's place for that voting member's review. The voting member of the COIRC under review will be treated like any other Member as defined by this Policy and will not be present for or take part in review of his/her Conflict of Interest disclosure or in the approval of any Management Plan necessary for the management of his/her actual, perceived, or potential Conflict of Interest.

COIRC Meeting Frequency

The COIRC will meet at least once every semester during the academic year unless there is insufficient business before the COIRC to warrant meeting in a given semester, and shall also convene when called upon by the Reviewer to conduct an initial review of a Member Conflict of Interest disclosure and conclude when a determination is submitted in the matter.

Review by the COIRC

1. When the Reviewer designates the COIRC to perform the initial review of Conflict of Interest disclosure questionnaire, the COIRC will review the completed disclosure identified by the Reviewer as a Category B or C conflict and proposed Management Plan in order to identify any actual, perceived, or potential Conflicts of Interest. If the COIRC agrees with the Reviewer's decision that an actual conflict exists, the COIRC will adopt the Member's proposed Management Plan, amend the Member's proposed Management Plan or develop an appropriate Management Plan, with input from the Member, or others, as needed.

2. If the Reviewer has requested expedited review of a Category A and/or Category B disclosure, the Chair of the COIRC or designee will review the disclosure and approve, amend, or veto the related Management Plan. These expedited disclosures will be reported to the full COIRC at its next meeting.
3. For situations in which the Reviewer has determined that a Member has an actual Conflict of Interest (Category C), OSU-CHS will not normally allow these activities if an acceptable Management Plan cannot be developed to avoid or eliminate the Conflict of Interest. All Category C disclosures must be reviewed and Management Plans approved by the full COIRC.
4. When necessary, the COIRC may discuss the disclosure and the development of a Management Plan with the Member involved and may also consult with others who may have relevant information.
5. The COIRC will attempt to conclude its review of a disclosure within *30 calendar days* after the matter is referred to the COIRC by the Reviewer. When the COIRC determines that a disclosure contains Category B and/or Category C disclosures, the COIRC will communicate this determination and its recommended Management Plan in writing to the Member, the appropriate Department or Unit Head, and the Reviewer, and to others on a “need to know” basis as allowed by law and OSU-CHS policies.
6. If the COIRC prescribes monitoring of a situation or an activity, it will describe specifically how the monitoring shall be performed and what records of the situation or activity are required.

Confidentiality

All information disclosed by an employee for the purpose of disclosure and management, and all official records of disclosure and management shall be considered a party of the employee’s personnel file and shall be deemed confidential. When sharing of COIRC current review status or outcome is required for internal coordination of approvals for research or educational activities, the COIRC will provide limited, non-specific information from the Member’s disclosure questionnaire and/or Management Plan. The recipient of such information shall maintain confidentiality, except as required for the performance of University duties or as required by the federal government. Unauthorized disclosure of any such information shall be deemed to be unethical behavior and a violation of this policy and subject to appropriate disciplinary action.

Disclosure questionnaires, Management Plans, and other Conflict of Interest records will be kept in locked file drawers and/or within electronic databases with firewall and password protection.

The University is required to make information available, upon request, to Federal agencies sponsoring work at the University regarding all conflicting interests associated with the funded project identified by the University and how those interests have been managed, reduced, or eliminated to protect the research from bias. The University maintains records of all financial disclosures and all actions taken by the University with respect to each conflicting interest for a reasonable period of time. For sponsored research activities, records will be retained for at least three (3) years from the date of submission of the final expenditures report or where applicable, from other dates specified by requirements of the sponsoring agency. The above notwithstanding, all such records shall be retained for a period of time as may be required by law.

Procedures

Disclosure

The key to recognizing and dealing with Conflicts of Interest is disclosure. Full, accurate disclosure and consultation regarding actual, potential, or perceived Conflicts of Interest is in the best interest of both Members and the University. A Member should complete and promptly submit a disclosure to the Reviewer on an annual basis and also after the Member has discovered or suspects that an actual, potential, or perceived Conflict of Interest exists or could arise from a situation or activity of that Member, their Family, or a Close Relation, including situations or activities that are reasonably foreseeable or are anticipated. This requirement applies to but is not limited to Conflicts of Interest arising out of a Member's, Family's, or Close Relation's association with a Third Party Organization.

Members shall also be required to disclose Significant Financial Interests under this policy or related University guidelines and the University will determine whether or not such Significant Financial Interests present a Conflict of Interest and, if so, develop plans for managing the conflict.

If at any time a Member believes or suspects that a situation or activity in which he/she is involved may present a Conflict of Interest, or if there is a significant change in the personal, financial, or fiduciary status of a Member, their Family or a Close Relation, with respect to a Third Party Organization, it should be promptly disclosed within *15 calendar days* to the Reviewer.

The University respects the privacy of Members and does not require the disclosure of financial or personal information that does not relate to an actual, potential, or perceived Conflict of Interest. Any Reviewer who receives such information as part of the disclosure, review, and management process is responsible for taking reasonable steps to maintain the confidentiality of the information. However, the Reviewer may be required to share, within the University community, financial and/or personal information contained in an individual disclosure when necessary for the Reviewer to make a complete and informed decision regarding the existence and management of an actual, potential, or perceived Conflict of Interest.

Review

Upon receipt of a complete disclosure, the Reviewer will determine whether he or she believes a Category A, B, or C Conflict of Interest exists. If the Reviewer determines that an actual, potential, or

perceived Conflict of Interest exists, the Reviewer will make a recommendation to the COIRC as to what conditions or restrictions, if any, should be imposed by the University to manage, reduce or eliminate such conflicts. The Member, with input from Reviewer if needed, shall develop a Management Plan for submission to the COIRC. If further guidance is needed, the Member and Reviewer should consult the COIRC before submission.

The Reviewer shall make a formal recommendation to the COIRC for disposition of the actual, potential, or perceived conflict and, if applicable, the corresponding Management Plan. A Member can expect disposition within a reasonable amount of time (normally, *45 calendar days*) provided the Reviewer has received a full and accurate disclosure from the Member.

Management

The COIRC shall make a decision regarding disposition of a disclosure based on the Reviewer's recommendation, the details regarding the Member's actual, potential, or perceived Conflict of Interest, and the proposed Management Plan. Proposed Management Plans and templates may be found on the OSU-CHS Conflict of Interest Questionnaire database and may be tailored to suit specific, actual, potential or perceived Conflicts of Interest as they arise.

Management Plans

At a minimum, all Management Plans submitted for review shall contain the following elements if applicable:

1. The role and principal duties of the conflicted individual in the activity;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in the activity;
4. Confirmation of the individual's agreement to the management plan;
5. How the management plan will be monitored to ensure compliance;
6. A list of all relevant publications, proposals, and presentations and, for each such project, a statement disclosing support received from or Significant Financial Interests in any Third Party Organization involved in the project upon publication;
7. A statement that the Member shall not engage in contractual negotiations on behalf of the University, including intellectual property negotiations, between the University and any Third Party Organization relevant to the proposed Management Plan;

8. A statement that the Member must notify students of any actual, potential, or perceived Conflict of Interest if students are to perform work on the project in question; and
9. Other information as needed.

Management Plans may also contain additional elements, including, without limitation, the following:

1. Oversight

- a. Providing copies to the COIRC of any financial or other disclosure statements submitted to a journal for article publication.
- b. Monitoring and oversight by a designated oversight manager, Department or Unit Head, supervisor, COIRC-appointed subcommittee, an independent monitor or COIRC.
- c. Quarterly, semi-annual, or annual review of the impact, if any, of Member's participation in activity on Member's responsibilities to University.

2. Modification to Scope of Work or Duties

- a. Reformulation of work plans or duties.
- b. Restrictions on analysis of contracts, bids, or research data.
- c. Close monitoring of projects by independent reviewers.
- d. Termination or reduction of involvement in relevant projects.
- e. Avoidance of inappropriate student involvement in projects.

3. Handling of Financial Interests

- a. Divestiture of the Financial Interest.
- b. Recusal from negotiations between the University and a Third Party Organization in which the Member, Member's Family, or Member's Close Relation has a Financial Interest.
- c. Disqualification from participation in the portion of the activity that would be affected by the Financial Interest.
- d. Disclosure of Financial Interest to all relevant parties involved in the activity.

4. Disclosure to Others

- a. Disclosure of Conflicts of Interest to others as required to perform University duties or as required by the Federal government.
- b. For projects involving human subjects research, disclosure of conflicts of interest directly to participants.

Reconsideration Process

A Member may ask for reconsideration of a Conflict of Interest determination and disposition made by the COIRC. A letter outlining the Member's reasons for requesting reconsideration must be submitted in writing to the COIRC within *15 calendar days* of a Member's receipt of the COIRC's determination

and disposition. Reconsideration with respect to a Conflict of Interest shall be separate from and not foreclose any other grievance process allowable by OSU-CHS policies or procedures.

After giving reconsideration to a Member, the subsequent decision of the COIRC regarding the Conflict of Interest and any related Management Plan shall be *final*. The COIRC shall notify the following individuals in writing within *15 calendar days* of reaching its final decision after reconsideration:

1. The Member who has the actual, potential, or perceived Conflict of Interest.
2. The relevant Department or Unit Head, member of the Member's Group, supervisor and/or Reviewer.
3. Other individuals on campus who have a "need to know" (e.g., the Vice President for Research).

Subrecipient Requirements

OSU-CHS shall obtain written assurance from any subrecipient of funds that subrecipient shall abide by this COI policy or that subrecipient certifies it institutes a Conflict of Interest policy that is compliant with all applicable federal and state laws and regulations.

Records and Retention

Records of disclosures, Reviewer recommendations, COIRC dispositions, conflict Management Plans, and all supporting documentation (e.g., meeting minutes) will be maintained in the University's Conflict of Interest Electronic Disclosure System managed by the Compliance Office.

Records shall be retained for a period of *3 years* following the later of the end of: (1) the situation presenting the actual, potential, or perceived Conflict of Interest; or (2) the management of the actual, potential, or perceived Conflict of Interest; or (3) "for at least three years from the date of submission of the final expenditures report" or other dates as specified by Federal law or regulation.

Non-Compliance

OSU-CHS expects Members to comply fully and promptly with this Policy, including the requirements of disclosure. Examples of breaches of the disclosure, review, and approval process *include, but are not limited to*:

1. Failures to comply with the process, whether by virtue of a Member's refusal to disclose or respond, or by his/her disclosing or responding with incomplete or knowingly inaccurate information;
2. Failures to address a Conflict of Interest as instructed; or

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3. Failures to comply with a prescribed conflict Management Plan.

The COIRC is authorized to establish standard procedures for reporting, investigating, and resolving alleged breaches. These standard procedures must provide the Member with an opportunity to respond to allegations in writing and, upon invitation by the COIRC, in person. If the COIRC determines that a breach occurred, the COIRC will include any written response submitted by the Member under investigation in its report specifying sanctions.

Sanctions for Non-Compliance

Members who deliberately or repeatedly fail to disclose fully and truthfully Conflict of Interest situations or fail to comply with any stipulated Management Plan for managing the disclosed conflict will be considered in serious breach of this policy, which may itself be considered ethical misconduct or professional dishonesty, and are subject to the applicable University disciplinary processes.

Sanctions may include disciplinary action ranging from a letter of reprimand to termination of employment. Additionally, instances of a deliberate breach of Policy related to a federally sponsored research program will be reported to the appropriate federal funding agency as required by applicable law or regulation and may result in the suspension of privileges to submit future grant proposals.

In addition to University sanctions, violations of full and prompt disclosure may result in the loss of grant funding and in sanctions regarding future funding from federal agencies. Members may also be subject to criminal sanctions or civil liability under federal or state law.

Allegations against an employee for breach of this policy should be reported in a confidential writing to the Director of Compliance at OSU-CHS.

DOCUMENT HISTORY:

Approved by OSU-CHS executive team: December 2016
Addendum added to incorporate PHS FCOI requirements: December 2020

NIH / Public Health Service (PHS) Financial Conflict of Interest (FCOI) Addendum

(This section applies only to PHS-funded research and supplements OSU-CHS Policy #9-70003)

Purpose and Authority

This Addendum is adopted to ensure Oklahoma State University Center for Health Sciences (OSU-CHS) complies with the Financial Conflict of Interest (FCOI) requirements applicable to research funded by the Public Health Service (PHS), including the National Institutes of Health (NIH), as set forth in 42 CFR Part 50 Subpart F and implemented through the NIH Grants Policy Statement (NIH GPS) §4.1.10.

This Addendum supplements, and does not replace, OSU-CHS Conflict of Interest Policy #9-70003. In the event of a conflict between this Addendum and the main policy, this Addendum shall govern with respect to PHS-funded research.

Scope and Applicability

This Addendum applies to all Investigators who are planning to participate in, or are participating in, PHS-funded research conducted at or on behalf of OSU-CHS, regardless of title or position.

For purposes of this Addendum, *PHS-funded research* includes research funded by NIH and any other agency of the Public Health Service to which 42 CFR Part 50 Subpart F applies.

Definitions

All definitions contained in Policy #9-70003 apply. In addition, for PHS-funded research:

- **Financial Conflict of Interest (FCOI)** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

These definitions are consistent with 42 CFR §50.603.

Disclosure of Significant Financial Interests

Investigators participating in PHS-funded research are required to disclose Significant Financial Interests (SFIs) to OSU-CHS:

1. No later than the time of application for PHS-funded research;
2. At least annually, during the period of award; and
3. Within fifteen (15) calendar days of discovering or acquiring a new SFI.

Disclosures must include SFIs held by the Investigator, the Investigator's spouse, and dependent children, in accordance with Policy #9-70003 and 42 CFR Part 50 Subpart F.

Institutional Review and Determination of Financial Conflicts of Interest

OSU-CHS, through the Director of Research Compliance and the Conflict of Interest Review Committee (COIRC), shall:

1. Review each disclosed SFI;
2. Determine whether the SFI is related to the Investigator's PHS-funded research; and
3. Determine whether a Financial Conflict of Interest exists.

An FCOI exists when OSU-CHS reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

Management of Financial Conflicts of Interest

All identified Financial Conflicts of Interest related to PHS-funded research must be managed, reduced, or eliminated through a written Management Plan approved by OSU-CHS in accordance with Policy #9-70003.

Except as permitted by regulation, PHS funds shall not be expended until the identified FCOI has been managed and, where required, reported to NIH.

Reporting of Financial Conflicts of Interest to NIH

OSU-CHS shall submit FCOI reports to NIH, including:

- Initial FCOI reports prior to the expenditure of PHS funds;
- Annual FCOI reports during the period of award; and
- Revised FCOI reports within sixty (60) days of identifying a new FCOI.

All reports shall be submitted in accordance with NIH-specified content, timing, and update requirements.

Retrospective Review and Mitigation

If OSU-CHS identifies non-compliance with this Addendum or with an approved Management Plan for PHS-funded research, OSU-CHS shall conduct a retrospective review within 120 days of identifying the non-compliance.

If the retrospective review determines that research was biased, OSU-CHS shall prepare and submit a mitigation report to NIH documenting the impact of the bias and actions taken to mitigate or eliminate its effect.

Training Requirements for PHS-Funded Research

Investigators engaged in PHS-funded research must complete FCOI training:

- Prior to engaging in PHS-funded research;
- At least every four (4) years thereafter; and
- Immediately if:
 - This policy or associated procedures are revised in a manner that affects Investigator requirements; or
 - OSU-CHS determines that an Investigator has not complied with this policy or an approved Management Plan.

Subrecipient Requirements

OSU-CHS shall ensure that each subrecipient participating in PHS-funded research provides written assurance that it has a Financial Conflict of Interest policy compliant with 42 CFR Part 50 Subpart F or agrees to follow OSU-CHS's Conflict of Interest policy and this Addendum.

Record Retention and NIH Access

OSU-CHS shall maintain records relating to all Investigator Disclosures of SFIs and OSU's actions in response to such disclosures until the later of: (1) at least three (3) years from the date the final expenditure report is submitted to the funding agency or non-agency sponsor, unless the funding agency or non-agency sponsor requires another retention period; (2) the resolution of any governmental action involving such records; (3) the date specified by federal or state laws or regulation (see, e.g., 51 O.S. §§24A.1-24A.30; 45 C.F.R. §75.361); or (4) any applicable state or institutional records retention schedule.

Institutional Certification

By submission of an application for PHS funding, OSU-CHS, through its Authorized Organizational Representative (AOR), certifies that:

- It has an up-to-date, written, and enforced Financial Conflict of Interest policy;
- It will promote and enforce Investigator compliance with FCOI requirements; and

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- It will fully comply with NIH GPS §4.1.10 and 42 CFR Part 50 Subpart F.

Compliance Reporting

Any suspected violation of this policy and related procedures must be reported to the Director of Research Compliance or the VPR. Anonymous reports may be submitted via the OSU/A&M EthicsPoint system.