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Research Policy and Operational Guidance: Financial Conflicts of Interest (FCOI) in PHS-Funded Research and Research Training

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Research Policy and Operational Guidance

Contents of this Manual

This manual contains research policy and operational guidance for Oakland University researchers and administrative staff regarding federal regulations governing objectivity in PHS-funded research.

Manual History

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Financial Conflicts of Interest (FCOI) in PHS-Funded Research and Research Training

1. Background and Rationale for Research Policy

In adhering to the university's commitment to the responsible conduct of research, Oakland University (OU) faculty, staff, students and administrators must make decisions that promote objectivity, accountability, integrity and transparency in research. One of the core areas of this commitment to research integrity is the disclosure and management of financial conflicts of interest (FCOI). Conflicts of interest are an inherent component of daily life and are not necessarily problematic. It is essential for members of the OU community to recognize the circumstances in which FCOI has the potential to influence the design, conduct or reporting of research. For those significant financial interests (SFI) that are deemed to be related or potentially related to research activities, a management plan is required in order to reduce or eliminate any actual or potential influence of the FCOI on the research, with the goal of ensuring the integrity of the research.

This research policy and operational guidance **applies to all Investigators who are planning to participate in, or who are participating in, research funded by the Public Health Service (PHS)**. PHS funding mechanisms include grants, cooperative agreements, career development awards, center grants, individual fellowship awards, and any activity where funding is available from PHS (e.g., National Institutes of Health, Agency for Healthcare Research and Quality, or Substance Abuse and Mental Health Services Administration). However, it **does not apply** to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) programs Phase I applications/awards.

This guidance describes OU's policies and procedures for compliance with the federal regulations on the "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (42 C.F.R. Part 50, Subpart F) and "Responsible Prospective Contractors" (45 C.F.R. Part 94). The 2011 regulations (referred to in this document as "**the final rule**") replace the 1995 regulations on FCOI and have an effective date of August 24, 2012. The final rule modifies the definition, thresholds, and requirements for disclosure, review, management, and reporting of financial interests held by investigators. An important difference is that the final rule places the responsibility on the institution, rather than the individual, for determining whether a disclosed financial interest is related to PHS-funded research. However, OU expects individuals to be proactive in complying with this guidance and the pertinent federal regulations with regard to the timely disclosure of financial interests, and the management of FCOI as directed.

The final rule requires a management plan, if applicable, to be developed and implemented before PHS grant funds are spent.

The **institutional responsibilities** of faculty and administrators that are covered by this research policy on FCOI include research activity, teaching, and service on OU committees. Research activity includes the design, conduct and reporting of research; faculty oversight of OU students and other trainees involved in research; and faculty mentoring of associates engaged in research or research training activities. This research policy applies not only to the potential or actual FCOI of OU employees, students and trainees, but also to FCOI involving their immediate family members.

2. Procedures

The Office of Research Administration (ORA) at OU oversees compliance with the final rule and this research policy. Part of ORA's mission is to ensure the responsible conduct of research through support, advocacy, and educational training programs. **OU investigators receiving PHS funding are required to participate in FCOI education and continuing FCOI educational training** in order to ensure up-to-date knowledge of institutional and sponsor expectations in an evolving regulatory and societal environment. Specific training requirements and the schedule for completion are detailed below. The figure provides a guide to investigators' responsibilities under this research policy and procedure.

For the purposes of this research policy, "**investigator**" refers to Program Directors/Principal Investigators and any other personnel who are responsible for the design, conduct or reporting of the PHS-funded work or proposed work. "Investigator" includes sub-grantees, contractors, consortium participants, collaborators, and consultants. The requirements of this policy also include financial interests held by the spouse and/or dependent children of these research personnel.

Investigators are responsible for providing timely disclosures of FCOI throughout the life of a research project. They must take reasonable steps to ensure that their collaborators and sub-recipients of funds also make timely disclosures. Investigators must adhere to the training requirements and any management plans as directed.

The Vice Provost for Research may serve as or appoint a Designated Official (DO) to administer this research policy and procedure. The DO is responsible for providing a review of all disclosures to determine whether a disclosed financial interest is related to the research and requires a management plan. The VPR or DO may conduct the review and/or convene a committee to conduct a review. The committee, if convened, must include at least one faculty member and one member who are familiar with the provisions of the final rule. The committee may be a standing committee or an ad hoc committee.

If a management plan is deemed to be necessary, the VPR, DO and/or a committee designated by the VPR or DO will draft an appropriate management plan for consideration

by the investigator. The investigator may request revisions to the management plan before the VPR, DO or committee makes a final decision on the management plan. Due to the necessity to provide timely reviews and appropriate dispositions of FCOI's, there is no appeal process once a final decision on a management plan is made. **The investigator(s) must accept the management plan in writing**, but if the investigator does not accept the final management plan, the VPR must take appropriate action to ensure that the investigator is not involved in the PHS-funded research.

The VPR, DO or other designee(s) is also responsible for **monitoring adherence to management plans** until completion of the project, which may be done on a for-cause or random basis. The VPR or DO is also responsible for overseeing compliance with other requirements of the final rule, and for reporting required information to PHS funding agencies.

The final rule also requires that institutions provide **public accessibility** of identified FCOI information for individual investigators, and compliance with this provision will be overseen by ORA.

a. Training Requirements

The final rule requires that investigators receiving PHS funding **complete training before engaging in the research and at least every four years**. Additionally, they must take required training immediately if the institution revises its FCOI policy such that requirements for investigators are changed, or an investigator is new to the institution, or an investigator is found not to be in compliance with this policy and procedure including any management plan. The nature of the FCOI training program is determined by the VPR, DO or other designee in accordance with federal and institutional requirements, and may be updated or revised as deemed necessary by the VPR.

At a minimum, training will include a review of this Research Policy and Operational Guidance; information about the investigator's disclosure responsibilities; and a review of the pertinent federal regulations. Investigators will be informed of the FCOI training requirements and how to access the training materials via the Research website, periodic emails, and in-person educational sessions.

b. Disclosure of Financial Interests

Investigators engaged in, or planning to engage in, PHS-funded research activity are required to disclose to ORA, per the schedule below, any **significant financial interests (SFI) related to the investigator's institutional responsibilities**. The requirement for disclosure of SFI applies to all persons engaged in PHS-funded research activity as "investigators," and includes (in aggregate) the financial interest of their spouses and/or dependent children. Investigators involved with research collaborators, sub-grantees, subcontractors or consultants must take reasonable steps to ensure compliance with the

final rule, and compliance with any applicable management plans established by OU. Disclosures are to be made via the “SFI Disclosure Form for PHS-Funded Investigators.”

SFI’s are required to be disclosed at the following time points:

- No later than at the time of application for PHS-funded research; and
- At least annually, regardless of any changes, during the period of award; and
- No later than 30 days after discovering or acquiring a new SFI at any point in the research process.

Completed forms must be provided to ORA via hand-delivery or e-mail (FCOI@oakland.edu). It is the investigator’s responsibility to submit the completed forms to ORA in a timely manner that is compliant with the timeline above.

Guidelines for determinations of relatedness:

Investigators must include in their disclosure their opinion about whether the SFI is related to the PHS-funded research. Additionally, for any disclosures regarding travel, the investigator’s chair, institute director, or dean must indicate whether he/she concurs with the investigator’s opinion about relatedness. These opinions will be considered as part of the institution’s determination of relatedness. Other considerations include but are not limited to the potential impact of the SFI on the research, the degree of risk associated with the potential impact, and whether the research involves human participants whose decision to participate might be affected by knowledge of the investigator’s FCOI.

Human subjects research:

When FCOI is related to human subjects research, the VPR or DO or designee will immediately forward the management plan to the OU Institutional Review Board (OU IRB). The OU IRB will consider the FCOI when reviewing the protocol, and may add (but not remove or decrease) requirements to the management plan. The IRB must communicate any decision to increase the requirements of the management plan to the VPR or DO, who will ensure that the investigator is notified about the revised management plan.

Compliance:

It is important for investigators to comply with these requirements for disclosure. Non-compliance will result in a retrospective review of the investigator’s records related to SFI, and could result in significant remedial actions and reporting to the sponsor as applicable. The VPR may designate an individual or may convene a committee to undertake retrospective reviews. Whenever OU identifies an SFI that was not disclosed in a timely manner by an investigator, or not previously reviewed by the institution, the determination of FCOI and implementation of a management plan, as applicable, must be completed within 60 days. Remedial and preventive actions may apply, at the discretion of the VPR, and any reporting requirements will be met.

In any case where the Department of Health and Human Services determines that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with a FCOI that was not managed or reported by the institution, the institution will require the investigator to:

- disclose the FCOI in each public presentation or publication of the research, and
- make every effort to amend previously published presentations to include the FCOI disclosure.

c. Disclosure of Significant Financial Interests (SFI)

The first step in the determination of whether an FCOI exists is the assessment of whether a financial interest disclosed by an investigator represents a significant financial interest (SFI) that is related to the PHS-funded research. Under the final rule, SFI is related to the PHS-funded research if an **institution reasonably determines** that the SFI could directly and significantly affect the design, conduct, or reporting of the research. The individual who has disclosed the SFI may be asked to assist with this determination, and/or the VPR or DO may convene a committee to review disclosures and assist in making the determinations about FCOI. If the VPR, DO or review committee determines that a SFI that is related to research rises to the level of FCOI, then a management plan is necessary.

According to the final rule, SFI means a financial interest consisting of one or more of the following interests of the investigator (including those of the Investigator's spouse and/or dependent children, in aggregate) that reasonably appears to be *related to the Investigator's institutional responsibilities*:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
 - For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse and/or dependent children) holds **any** equity interest (e.g., stock, stock option, or other ownership interest)—there is no minimum threshold; or

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income **that exceeds \$5,000** related to such rights and interests.

Travel:

Investigators also must disclose the occurrence of any sponsored or funded travel (there is no minimum threshold) related to their institutional responsibilities. This disclosure requirement applies to travel expenses that are paid on behalf of, or reimbursed to, the investigator by any for-profit or not-for-profit entity. This does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Disclosures regarding travel must be made within 30 days of the travel, or may be prospectively reported. The disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the inclusive dates. The investigator and his/her department chair, institute director, or dean must indicate on the disclosure form whether, in their opinions, the travel meets the definition of an FCOI with the PHS-funded research. The VPR, DO, or designee may ask for more information about the travel, and will make the final determination about FCOI and the need for a management plan.

Exclusions:

SFI does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by OU to the investigator if the investigator is currently employed or otherwise appointed by OU, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement accounts, so long as the investigator does not directly control the investment decisions made in these vehicles;
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

d. Reporting Requirements to PHS Sponsors

The VPR or DO is responsible for institutional reporting of FCOI and its management to the PHS sponsors. Reporting requirements include initial, annual (ongoing) and revised FCOI reports, including all reporting elements required by the final rule. Specifically, reports must be provided to the PHS sponsor at the following time points:

- Prior to the expenditure of funds
- Within 60 days of identification for an investigator who is newly participating in the project
- Within 60 days for new, or newly identified, FCOI's for existing investigators
- At least annually (at the time that the institution is required to submit the annual progress report, or equivalent) until the completion of the project
- Following a retrospective review to update a previously submitted report, if appropriate

Reporting to PHS about Management Plans:

The key elements of a management plan for PHS funded research that must be reported to the PHS sponsor are as follows:

- The role and principal duties, within the research project, of the individual who has the FCOI
- The conditions of the management plan
- How the management plan will safeguard objectivity in the research
- Confirmation that the conflicted individual has agreed to the management plan
- How the management plan will be monitored to ensure compliance
- Other information as needed

Other Reporting Requirements:

The VPR or DO will notify the PHS sponsor promptly if:

- bias is found with the design, conduct or reporting of the research. This notification will include a Mitigation Report; or
- an investigator fails to comply with the institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the research.

e. Maintenance of Records

All FCOI-related records will be securely maintained by ORA for a period of three years from the date that the final expenditures report is submitted to the PHS, or longer if required by regulation, grant or contractual agreement.

3. Guidelines for Management Plans

The VPR, DO and/or committee appointed to develop a management plan has the latitude to require reasonable actions to protect the integrity of the research. The level of FCOI that is deemed manageable may be different for basic research than for clinical research. Management plans might include but are not limited to the following requirements, as applicable to each situation:

- public disclosure of FCOI in presentations, publications, or other settings;
- disclosure of FCOI to collaborators, students, and/or trainees associated with the research;
- appointment of an independent monitor or oversight committee;
- more frequent (than annual) disclosures of SFI to the DO;
- changes in the roles of the conflicted investigator(s);
- reduction or elimination of the financial interest;
- inclusion of information about the FCOI in consent forms for human participants in research.

Failure to comply with a management plan may entail sanctions for the non-compliant investigator. In these cases, the VPR will consult with the Senior Vice President for Academic Affairs and Provost, and any other relevant units of university administration.

4. Retrospective Review of Financial Conflicts of Interest

The VPR, DO or designee will complete a retrospective review within 120 days of the determination that SFI's were not disclosed in a timely manner, or were not previously reviewed per this policy; or whenever an FCOI is not identified or managed in a timely manner. The retrospective review will ascertain whether it is probable that research performed during a period of noncompliance was biased by the FCOI in its design, conduct or reporting, and the extent of probable harm. If bias is found, then the VPR, in consultation with the Senior Vice President for Academic Affairs and Provost and other relevant administrative units of the university, will determine the appropriate remedy.

5. Subrecipient Requirements

Subrecipient organizations are required to comply with the final rule on FCOI. The VPR and/or the DO at OU will determine whether the subrecipient will follow OU's FCOI research policy and procedures, or whether the subrecipient will follow its own FCOI policy. OU will allow the subrecipient to rely on its own FCOI policy if it can be demonstrated to OU's DO that this policy complies with the final rule. In addition, the subrecipient must agree to report its identified FCOI's in a time frame that allows OU to report these to the PHS sponsor as required by the regulation. A written agreement between the institutions may be necessary.

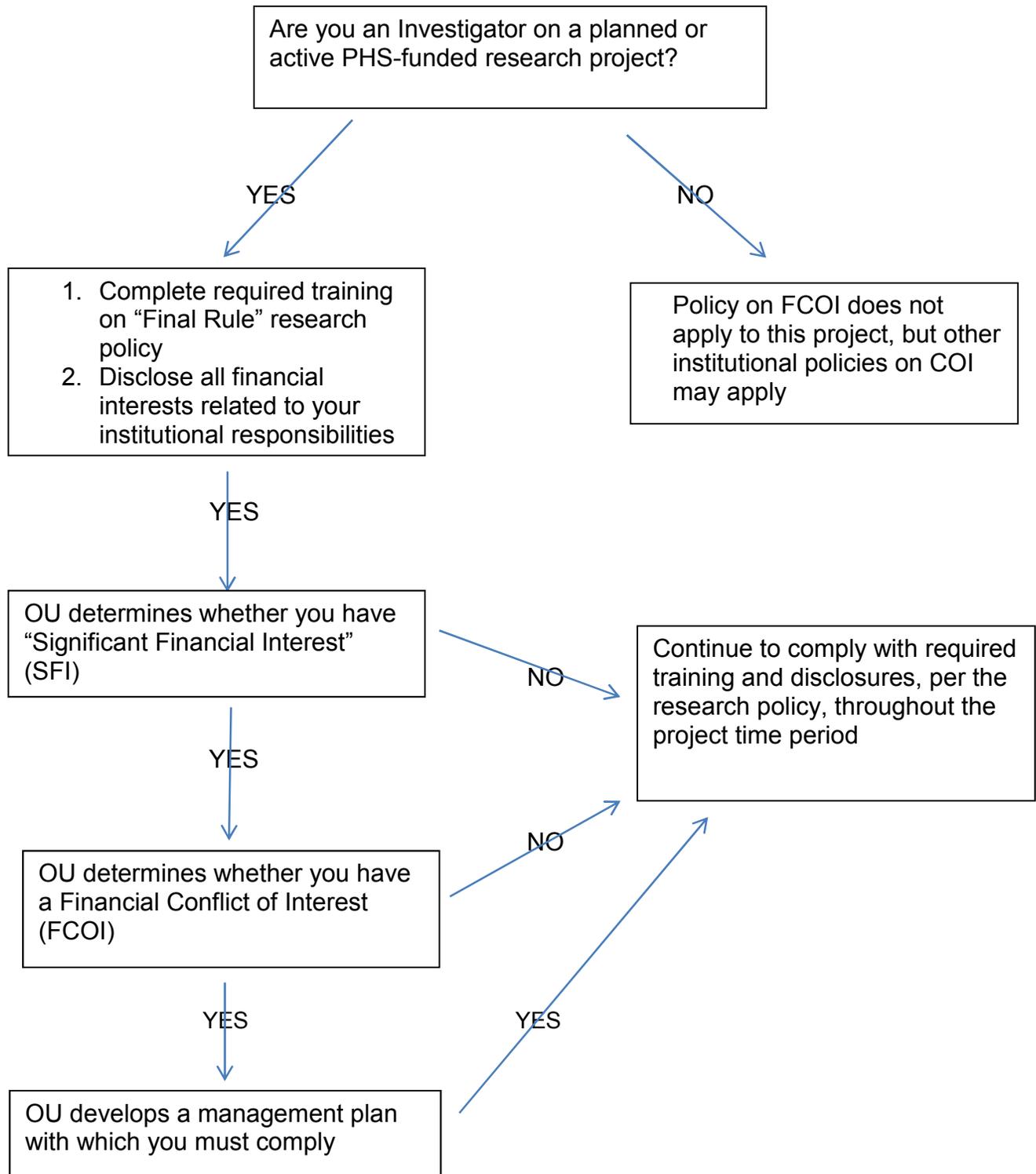
6. Public Accessibility

This research policy on FCOI will be available on OU's publicly available research website, but a copy will also be made available within 5 business days of a request if the requestor is unable to access the website or the policy. Prior to the expenditure of any funds under a PHS-funded research project with associated FCOI's, OU will ensure public accessibility of information concerning any FCOI associated with that project. Information concerning identified FCOI's held by investigators will be made available within 5 days of a written request. This information will remain available for three years from the date that it was most recently updated. The required elements will be provided, as follows:

- 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, 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.

Figure: Flow Chart for Investigator and OU Responsibilities

[“OU” refers to the Vice Provost for Research or Designee(s)]



SFI Disclosure Form for PHS-Funded Investigators

Investigators engaged in, or planning to engage in, PHS-funded research activity are required to disclose to the Office of Research Administration, per the schedule below, any **significant financial interests (SFI) related to the investigator's institutional responsibilities**. The requirement for disclosure of SFI applies to all persons engaged in PHS-funded research activity as "investigators," and includes (in aggregate) the financial interest of their spouses and/or dependent children. Investigators involved with research collaborators, sub-grantees, subcontractors or consultants must take reasonable steps to ensure compliance with the final rule, and compliance with any applicable management plans established by OU. Disclosures are to be made via the "SFI Disclosure Form for PHS-Funded Investigators."

SFI's are required to be disclosed at the following time points:

- No later than at the time of application for PHS-funded research; and
- At least annually, regardless of any changes, during the period of award; and
- No later than 30 days after discovering or acquiring a new SFI at any point in the research process.

It is the investigator's responsibility to comply with these rules and to submit the completed forms to ORA in a timely manner that is compliant with the timeline above. Completed forms must be provided to ORA via hand-delivery or e-mail (FCOI@oakland.edu).

Date: _____

Investigator's name: _____

Investigator's title at Oakland University: _____

Investigator's e-mail at OU: _____ Phone number: _____

Title of project: _____

PHS Sponsor (e.g., NICHD): _____

PHS Grant Number: _____

Starting date of project: _____ End date of project: _____

Investigator's role on project (provide general role, such as "Principal Investigator" or "Key Personnel," and then explain what you will be doing on the project, in a single paragraph):

List subrecipients, or "none":

Disclosure of Significant Financial Interests (SFI)

SFI means a financial interest consisting of one or more of the following interests of the investigator (including those of the Investigator's spouse and/or dependent children, in aggregate) that reasonably appear to be related to the Investigator's *institutional responsibilities*. Note that you are being asked about all SFI related to your responsibilities at OU, not just financial interests that may be related to the PHS-funded project. Answer all of the questions below for each category of SFI, and then complete the table:

(1) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.

Check all of the following that apply with regard to category #1:

- I personally have no SFI to disclose in this category.
- My immediate family members have no SFI to disclose in this category.
- I personally have SFI to disclose in this category. (list in table below)
- My immediate family members have SFI to disclose in this category. (list in table below)

(2) Remuneration that includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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.

Check all of the following that apply with regard to category #2:

- I personally have no SFI to disclose in this category.
- My immediate family members have no SFI to disclose in this category.
- I personally have SFI to disclose in this category. (list in table below)
- My immediate family members have SFI to disclose in this category. (list in table below)

(3) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse and/or dependent children) holds **any** equity interest (e.g., stock, stock option, or other ownership interest).

Check all of the following that apply with regard to category #3:

- I personally have no SFI to disclose in this category.
- My immediate family members have no SFI to disclose in this category.
- I personally have SFI to disclose in this category. (list in table below)
- My immediate family members have SFI to disclose in this category. (list in table below)

(4) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income that exceeds \$5,000 related to such rights and interests.

Check all of the following that apply with regard to category #4:

- I personally have no SFI to disclose in this category.
-

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My immediate family members have no SFI to disclose in this category.

I personally have SFI to disclose in this category. (list in table below)

My immediate family members have SFI to disclose in this category. (list in table below)

Travel: Investigators also must disclose the occurrence of any sponsored or funded travel (there is no minimum threshold) related to their institutional responsibilities. This disclosure requirement applies to travel expenses that are paid on behalf of, or reimbursed to, the investigator by any for-profit or not-for-profit entity. This does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Although the exact monetary value may not be readily available, OU may request more information during its review of the disclosure. If you have more than one disclosure for travel, attach additional pages. Answer all of the questions below:

- purpose of the trip:
- identity of the sponsor/organizer:
- destination:
- duration of the trip (give dates of travel):

Do you believe that the travel meets the definition of a financial conflict of interest with the PHS-funded research? Yes No

Provide a rationale for your answer:

The **Chair of your Department, Director of your Center or Institute, or your Dean**, must also review your travel disclosure and answer this question:

Do you believe that the investigator's travel meets the definition of a financial conflict of interest with the PHS-funded research? Yes No

Provide a rationale for your answer:

Signature of Chair, Director or Dean

Printed name and title

Date

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DISCLOSURE FORM FOR PHS

Exclusions:

SFI does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by OU to the investigator if the investigator is currently employed or otherwise appointed by OU, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;
 - income from investment vehicles, such as mutual funds and retirement accounts, so long as the investigator does not directly control the investment decisions made in these vehicles;
 - income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education [as defined at 20 U.S.C. 1001(a)], an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
 - income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
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DISCLOSURE FORM FOR PHS

Table: SFI disclosures for PHS funded research

Instructions: For each category described above, for which you indicated that you and/or your immediate family (in aggregate) **have SFI related to your institutional responsibilities** at OU, provide the dollar amount of your SFI in the column under the appropriate dollar range (e.g. if you have SFI in the amount of \$6,500 in category #1, enter this amount in the column marked "\$5,000-\$9,999"). Then provide your opinion about whether the SFI is related to the PHS-funded research project. If you need more rows for your disclosures, attach additional copies of the table.

| Category | \$5,000-\$9,999 | \$10,000-\$19,999 | \$20,000-\$100,000 | >\$100,000 | Other* | Related to PHS-funded project? | |
|---|-----------------|-------------------|--------------------|------------|--------|--------------------------------|----|
| | | | | | | Yes | No |
| 1 publicly traded entities | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| 2 remuneration | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| 3 non-publicly traded entities | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| 4 intellectual property | | | | | | | |
| | | | | | | | |
| | | | | | | | |

***Other:** Put a check in this column if the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value, or if the interest is one that does not have a minimum threshold per the final rule.

Comments that you think would be helpful to the FCOI reviewer:

Signature of Investigator

Date
