



Revision:
11/30/2017

Effective Date:
8/24/2012

Research Office

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

Date of this issuance: 24-Aug-2012	
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Revision Number	Revision Date	Summary of Changes	Author
Original			D. Nelson
1	9 25 12	Clarify effective date of policy and add "United States" to exclusions for SFI & travel	D. Nelson
2	8 10 16	Addition of non PHS agencies that have adopted the final rule; updated SFI disclosure forms and procedures; change in Vice Provost for Research to Associate Vice President for Research; format revisions; addition of retrospective review	R. Sandborg
3	11 30 17	Addition of \$5000 de minimus threshold for reimbursed or sponsored travel; Change Office of Research Administration to Research Office; Minor editorial changes.	R. Sandborg

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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 the research.

This research policy and operational guidance **applies to all Investigators who are planning to participate in, or who are participating in, new research projects funded by the Public Health Service (PHS) on or after August 24, 2012.** 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). This research policy also applies to non-PHS agencies that have adopted the PHS Policy on FCOI. However, it **does not apply** to Phase 1 Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) 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. This research policy applies not only to the potential or actual FCOI of OU employees, students, trainees, and other individuals meeting the definition of investigator but also to FCOI involving their spouse and dependent children.

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. .

2. Procedures

The Research Office at OU oversees compliance with the final rule and this research policy. Part of the Research Office'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 elsewhere in this policy as well as other 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. "Investigators" includes sub-grantees, contractors, consortium participants, collaborators, and consultants. Principal Investigators (PIs) should consider the degree of independence when determining whether these other personnel meet the definition of "investigator." 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 their financial interests 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. All investigators must adhere to the training requirements and management plan as directed.

The Associate Vice President for Research (AVPR) 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 any disclosed financial interest is related to the research and requires a management plan. The AVPR 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 is 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 AVPR, DO and/or a committee designated by the AVPR or DO will draft an appropriate management plan for consideration by the investigator. The investigator may request revisions to the management plan before the AVPR, 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 appeals 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 AVPR must take appropriate action to ensure that the investigator is not involved in the PHS-funded research.

The AVPR, 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 AVPR 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 the Research Office.

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 AVPR, DO or other designee in accordance with federal and institutional requirements, and may be updated or revised as deemed necessary by the AVPR.

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 Office 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 the Research Office any **significant financial interests (SFI) throughout the life of a research project. A SFI is a financial interest, as defined below, that reasonably appears to be 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 the investigator's financial interests and the financial interests of the investigator's spouse and/or dependent children (in aggregate). PIs 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” in accordance with the schedule below.

Investigators must submit a SFI Disclosure Form at the following time points:

- No later than at the time of application for PHS-funded research;
- At least annually, regardless of any changes, during the period of award;
- No later than 30 days after discovering or acquiring a new SFI at any point in the research process;
- At the time a new investigator is added to the PHS-funded research; and
- Within 30 days of new reimbursed or sponsored travel that meets the \$5000 de minimus threshold.

Investigators who disclose a SFI will be requested to submit additional information regarding their SFI including 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. These determinations will be made at the just-in-time phase of the award process for PHS-funded proposals or prior to the expenditure of funds for awards made by funding agencies that have adopted the final rule to determine if a FCOI exists and may require a management plan. Additional information regarding SFIs must be submitted using “SFI Disclosure Form for PHS-Funded Investigators Appendix A.”

Completed forms must be provided to the Research Office via hand-delivery or e-mail to FCOI@oakland.edu or the DO. It is the investigator’s responsibility to submit the completed forms to the Research Office in a timely manner that is compliant with the timeline above. Forms sent electronically should come from the investigator’s institutional e-mail account.

Human subjects research:

When a FCOI is related to human subjects research, the AVPR 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 AVPR or DO, who will ensure that the investigator is notified about the revised management plan.

Compliance:

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. Definitions of Significant Financial Interests (SFI) and FCOI Determination

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 sponsored or reimbursed travel related to their institutional responsibilities that exceeds \$5000 when aggregated from a single

entity. Travel that is below the \$5000 de minimus threshold but when aggregated with an investigator's other financial interests with the same entity exceeds \$5000 must be disclosed. 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 disclosure requirement also applies to the Investigator's spouse and/or dependent children. 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 in the United States.

Investigators who are planning on participating in PHS-funded research must disclose the occurrence of any sponsored or reimbursed travel meeting the \$5000 de minimus threshold in the previous twelve month period no later than at the time of application for PHS-funded research. Investigators must submit updated disclosures regarding travel within 30 days of each new occurrence once the \$5000 de minimus threshold from a single entity has been reached. The disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the inclusive dates. Travel expenses that require reporting include, but are not limited to registration, transportation, lodging and other travel related expenses. 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 AVPR, 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;
- any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization;
- 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 in the U.S.; 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 in the United States.

d. FCOI Determination

The first step in the determination of whether an FCOI exists is the assessment of whether a SFI disclosed by an investigator is related to the PHS-funded research. Under the final rule, a SFI is related to the PHS-funded research if an **institution reasonably determines** that the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. The individual who has disclosed the SFI may be asked to assist with this determination. A financial conflict of interest exists when the institution reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of the PHS-funded research. The DO may make these determinations, and/or the AVPR or DO may convene a committee to review disclosures to assist in making the determinations about FCOI. If the AVPR, DO or review committee determines that a SFI that is related to research and rises to the level of FCOI, then a management plan may be necessary. Management plans must be reported to the PHS funding agency and include the required elements specified below.

e. Guidelines for Management Plans

The AVPR, 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.

Noncompliance with this policy is defined when an FCOI is not identified or managed in a timely manner for any of the following reasons: 1) failure by the Investigator to disclose an SFI, 2) failure by the Institution to review or manage an FCOI, or 3) failure to comply with the management plan.

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

f. Retrospective Review of Financial Conflicts of Interest

If a SFI is not disclosed by an investigator in a timely manner or is not reviewed during an ongoing PHS-funded research project in accordance with OU's policy, the SFI must be reviewed by the AVPR, DO or an ad hoc committee within 60 days to determine whether it is related to the PHS-funded research and if so, whether a FCOI exists. If it is determined that a FCOI exists, a management plan must be developed and implemented to manage the FCOI.

In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the investigator to disclose a SFI that is determined to constitute a FCOI, failure by OU to review or manage such a FCOI or failure by the investigator to comply with a FCOI management plan, a retrospective review of the investigator's activities and the PHS-funded research project must be conducted within 120 days of OU's determination of noncompliance. The purpose of the retrospective review is to determine whether any portion of the PHS-funded research conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

The retrospective review will be documented and include the following elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, previously submitted FCOI reports must be updated with the PHS funding agency including the actions taken to manage the FCOI going forward. If bias is found, the PHS funding agency must be notified immediately and a mitigation report submitted. The mitigation report must include at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the effect of the bias. FCOI reports will subsequently be submitted to the PHS funding agency annually.

g. Reporting Requirements to PHS Sponsors

The AVPR or DO is responsible for institutional reporting of FCOI and its management to the PHS funding agency. 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 funding agency at the following time points:

- Prior to the expenditure of funds;
- Within 60 days for an identified FCOI 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 is designed to 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 with an identified FCOI that 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.

h. Maintenance of Records

All FCOI-related records will be securely maintained by the Research Office 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. Subrecipient Requirements

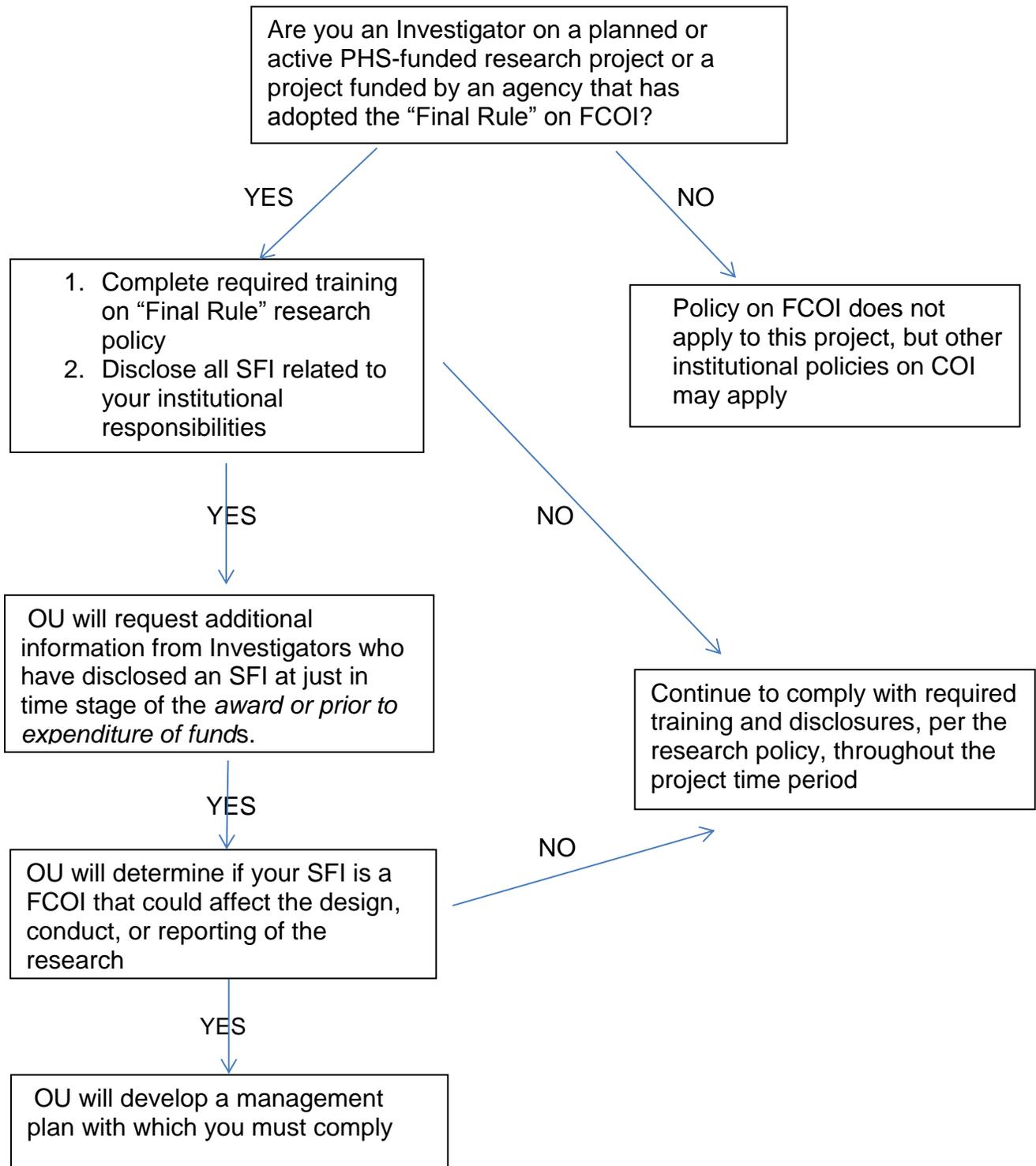
Subrecipient organizations are required to comply with the final rule on FCOI. The AVPR and/or the DO at OU will determine whether the subrecipient will follow OU's FCOI research policy and procedures, or whether the subrecipient will follow its own FCOI policy. OU will allow the subrecipient to rely on its own FCOI policy if it can be demonstrated to OU's DO that this policy complies with the final rule. In general, if a subrecipient institution has certified compliance with the final rule with the Federal Demonstration Partnership (FDP) FCOI Institutional Clearinghouse, OU will allow that institution to follow their own FCOI policy. In addition, the subrecipient must agree to report its identified FCOIs in a time frame that allows OU to report these to the PHS sponsor as required by the regulation. When OU relies upon the subrecipient's policy, a written agreement between the institutions will be required.

4. 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 Associate Vice President for Research or Designee(s)]



OAKLAND UNIVERSITY RESEARCH OFFICE

SFI Disclosure Form for PHS-Funded Investigators

Instructions

The Final Rule, *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors* (42 CFR Part 50, Subpart F and 45 CFR, Part 94) went into effect August 24, 2012. The Final Rule requires all investigators engaged in, or planning on engaging in, PHS-funded research to disclose **significant financial interests (SFI)** related to the Investigator's institutional responsibilities. The requirement to disclose SFI also includes disclosure of all SFI of an investigator's spouse and/or dependent children. Investigators must disclose their SFIs over the previous twelve month period no later than at the time of application for PHS-funded research or within 30 days of acquiring or discovering a new SFI for existing awards. This disclosure requirement also applies to certain non-PHS agencies that have adopted the Final Rule (e.g. AHA, ACS).

What is an investigator?

An investigator is defined as 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 any PHS agency, such as NIH. Investigators include principal investigators (PIs), co-investigators, sub-grantees, contractors, consortium participants, collaborators, and consultants. PIs should consider the degree of independence to which these other personnel contribute to the project when determining whether they meet the definition of investigator. PIs must ensure that all other investigators engaged in a PHS-funded activity comply with the Final Rule regarding SFI disclosure.

What are institutional responsibilities?

Institutional responsibilities are the investigator's professional responsibilities conducted on behalf of OU including but not limited to the design, conduct and reporting of research, teaching, and service on OU committees. Institutional responsibilities include the expertise and credentials upon which the investigator's employment with OU is based.

What is an entity?

Entity means any domestic or foreign, public or private, organization (excluding a federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

What is a Significant Financial Interest (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 this definition includes all SFI related to responsibilities at OU, not just financial interests that may be related to the PHS-funded project.

- (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 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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 or stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

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- (2) 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 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any equity interest (e.g., stock, stock option, or other ownership interest).
 - (3) **Intellectual property** rights and interests (e.g., patents, copyrights), upon receipt of income that exceeds \$5000 related to such rights and interests.
 - (4) **Reimbursed or sponsored travel** related to an investigator's institutional responsibilities that exceeds \$5000 when aggregated from a single entity over the previous 12 months for new proposals or within 30 days of each new occurrence for existing awards. Travel that is below the \$5000 de minimus threshold but when aggregated with an investigator's financial interests with the same entity exceeds the \$5000 de minimus must be disclosed. Investigators must submit updated disclosures regarding travel within 30 days of each new occurrence once the \$5000 de minimus threshold from a single entity has been reached. 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 in the US. Travel reimbursed or sponsored by a foreign institution of higher education or the government of another country must be reported. Although the exact monetary value may not be readily available, OU may request more information during its review of the disclosure.

What is not a Significant Financial Interest?

Significant financial interests do not include:

- 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 in the US; 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 in the US.

When do disclosure forms need to be submitted?

Disclosure forms must be submitted at the following time points:

- No later than at the time of application for PHS-funded research;
- At least annually, regardless of any changes, during the period of award;
- No later than 30 days after discovering or acquiring a new SFI;
- At the time a new investigator is added to a project; and
- Within 30 days of new reimbursed or sponsored travel that meets the \$5000 de minimus threshold.

How are SFIs reported?

SFIs are required to be disclosed using the "SFI Disclosure Form for PHS-Funded Investigators." Investigators will be contacted to complete additional information (Appendix A) for any reported SFIs.

To whom are disclosure forms submitted?

SFI Disclosure Forms should be submitted to FCOI@oakland.edu or Gonzales@oakland.edu.

market value.

No

Yes: Complete Appendix A (at the just-in-time phase for new grant application or within 30 days for an existing award)

Non-Publicly Traded Entity

Have you, your spouse, and/or your dependent children received any remuneration from a non-publically traded entity in the preceding 12 months that when aggregated exceeds \$5000? Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

No

Yes: Complete Appendix A (at the just-in-time phase for new grant application or within 30 days for an existing award)

Do you, your spouse, and/or your dependent children currently own or do you, your spouse, and/or your dependent children hold **any** equity interest in a non-publicly traded entity? Equity interest includes any stock, stock options, or other ownership interest.

No

Yes: Complete Appendix A (at the just-in-time phase for new grant application or within 30 days for an existing award)

Intellectual property

Have you, your spouse, and/or your dependent children received income from intellectual property rights and interests (e.g., patents, copyrights) in the past 12 months that exceed \$5,000 related to such rights and interests?

No

Yes: Complete Appendix A (at the just-in-time phase for new grant application or within 30 days for an existing award)

Travel

Have you, your spouse and/or dependent children received reimbursement or been sponsored for travel related to your institutional responsibilities? For new proposals, travel that exceeds \$5000 when aggregated from a single entity in the previous 12 months must be disclosed? Travel that is below the \$5000 threshold but when aggregated with other financial interests with the same entity exceeds the \$5000 threshold in the previous 12 months must also be disclosed. Investigators must submit updated disclosures regarding travel within 30 days of each new occurrence once the \$5000 de minimus threshold from a single entity has been reached. 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.

No

Yes: Complete Appendix A

Certification

By typing or signing your name below, you attest that the information provided on this form is accurate to the best of your knowledge. Furthermore you will disclose any newly discovered or acquired SFIs within 30 days.

You have read OU's "Research Policy and Operational Guidance: Financial Conflicts of Interest (FCOI) in PHS-Funded Research and Research Training."

Typed Name or Signature of Investigator: _____
 Date: _____

OAKLAND UNIVERSITY
OFFICE OF RESEARCH ADMINISTRATION

SFI Disclosure Form for PHS-Funded investigators
Appendix A

Project and Funding Information

Title of Project: _____
 PHS or Other Sponsor (e.g., NICHD, AHA, ACS): _____
 Subcontract of PHS funds from: _____

Investigator Information

Principal
 Other (Co-investigator, consultant, statistician, etc.): _____

Name: _____
 Title: _____
 Department: _____
 Institutional Affiliation: _____
 E-mail Address: _____
 Phone Number: _____

Role on the Project

Briefly describe your **role on project** (co-investigator, etc.) and your primary responsibilities: _____

Type of Disclosure

New Award Annual New investigator added to project
 Discovery of an existing SFI Acquisition of new SFI Reimbursed or sponsored travel

Disclosure Information

For each Significant Financial Interest (SFI) category for which you indicated that you, your spouse, and/or your dependent children (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 in the table below (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 by checking "yes" or "no" in the far right hand side of the table. Attach additional copies of the table if more rows are needed for disclosures.

Category	\$0-\$4,999	\$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	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Remuneration and Equity Interest	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 Non-Publicly Traded Entities Remuneration	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 Non-Publicly Traded Entities Equity Interest						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 Intellectual Property Income	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	N/A					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*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.

Determination of Relatedness and Financial Conflict of Interest

A Financial Conflict of Interest (FCOI) exists when OU, through its Designated Official(s) (DO), Associate Vice President for Research (AVPR), or ad hoc committee reasonably determines that an Investigator's SFI is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research. To assist in making this determination, answer the questions listed below.

What is the name of the outside entity with which the investigator has a SFI? _____

What is the principal business of the outside entity? _____

Who has the SFI?

- You
- Your spouse
- Your dependent children

What is the nature of the SFI?

Compensation/Remuneration/Honoraria/Paid Authorship
Describe your services: _____

Stock, Stock Options, Equity or Other Ownership Interest
Describe: _____

IP licensing fees and/or royalty payments
Describe: _____

Special relationship with the outside entity such as directorship, officer, trustee, management role
Describe: _____

Other: _____

Does the entity have any products that are involved in the research such as equipment, facilities, drugs, devices, software, proprietary data, etc.?

-
- No
 Yes: Describe: _____

Will the research evaluate any products that are currently being developed by the outside entity?

- No
 Yes: Describe: _____

Will the entity manufacture or commercialize any drug, device or product that may be associated with or result from the research?

- No
 Yes: Describe: _____

Could the entity be affected by the outcome of the PHS-funded research in any way?

- No
 Yes: Describe: _____

For privately held entities, could your SFI have influence over the entity's decisions, or business or financial outlook?

- No
 Yes: Describe: _____

Do you, your spouse or your dependent children have an inventive or ownership interest in any intellectual property that will be utilized in the PHS-funded research?

- No
 Yes: Describe: _____

Who owns the IP to be used in the PHS-funded research? _____

Does the entity hold rights to a pending application or issued patent to an invention, license right, or copyright for software of yours, your spouse or your dependent children?

- No
 Yes: Describe: _____

Please list any previous and pending patents and any recently submitted disclosure(s) of inventions of yours, your spouse's and/or your dependent children. _____

Are human subjects involved in the research?

- No
 Yes: Describe: _____

Do you believe that your SFI could be related to or be perceived to be related to the design, conduct or reporting of your PHS-funded research?

- No: Explain: _____
 Yes: Explain: _____

Reimbursed or Sponsored Travel

Investigators also must disclose the occurrence of sponsored or reimbursed travel related to their institutional responsibilities that exceeds \$5000 when aggregated from a single entity. Travel that is below the \$5000 threshold but when aggregated with an investigator's other financial interests with the same entity that exceeds the \$5000 de minimus threshold must also be disclosed. The \$5000 de minimus threshold applies to the previous 12 months for new awards or within 30 days of each new occurrence once the \$5000 de minimus threshold has been reached for existing awards. 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 in the US. 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.

If you have disclosed sponsored travel, please complete the table below.

Sponsor/Organizer	Destination of trip	Duration of trip (give dates)	Purpose of trip

Provide the value of the reimbursed or sponsored portion of the travel, if known: _____

What is the name of the entity from whom the travel was sponsored or reimbursed? _____

Please provide the dollar amount of financial interest related to the entity from whom the travel was sponsored or reimbursed. _____ N/A

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

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: _____

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

Certification

By typing or signing your name below, you attest that the information provided on this form is accurate to the best of your knowledge and that all signatures – typed and/or handwritten- have been directly obtained from all individuals for any document included in this project. Furthermore, you will disclose any newly discovered or acquired SFIs within 30 days. You have read OU's "Research Policy and Operational Guidance: Financial Conflicts of Interest (FCOI) in PHS-Funded Research and Research Training."

Typed Name or Signature of Investigator: _____

Date: _____

Typed Name or Signature of Department Chair, Dean or Center Institute or Director: _____

Date: _____