

Office of Research Administration

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

1. Background and Rationale for Research Policy

The faculty, staff, administrators and students of Oakland University (OU) must act to promote objectivity, accountability, integrity and transparency in research. One focus of this commitment to research integrity is the disclosure and management of financial conflicts of interest (FCOI). The National Science Foundation (NSF) encourages enhanced involvement with business and industry; this involvement, however, increases the risk of FCOI. Therefore, NSF developed an **Investigator Financial Disclosure Policy** to help ensure the appropriate management of actual or potential conflicts of interest. The NSF policy defines an investigator as the program director or Principal Investigator (PI), co-Principal Investigator/Co-Project Director or any other person, regardless of position or title, who is responsible for the design, conduct or reporting of any research or educational activities funded or proposed for funding by NSF.

NSF requires each grantee institution employing more than 50 persons to have an appropriate written and enforced policy on conflict of interest. The purpose of the policy is to ensure that all conflicts of interest for each award are managed, reduced or eliminated prior to the expenditure of the award funds. The Office of Research Administration (ORA) at OU maintains appropriate policy and procedures on FCOI and oversees compliance with NSF regulations. This policy applies to all individuals who receive, or are planning to receive, funding from NSF.

This guidance describes the policy and procedures that are outlined by the NSF Grant Proposal Guide and includes the definitions, thresholds and requirements for disclosure of Significant Financial Interests (SFI) held by investigators. Responsibility for review of these disclosures, and development of a management plan if a Significant Financial Conflict of Interest (SFCOI) is found to exist, rests with ORA.

2. Procedures

The Associate Vice President for Research (AVPR) may serve as, or appoint, a Designated Official (DO) to administer NSF research policy. This research policy and operational guidance **applies to all investigators who are planning to participate in, or who are participating in research or educational activities funded by the NSF**. However, **it does not apply** to the Small Business Innovative Research Program or Small Business Technology Transfer Program.

For purposes of this research policy, “**Investigator**” refers to Program Directors/Principal Investigators, Co-Principal Investigators/Co-Project Directors and any other person at the institution, regardless of title or position, who is responsible for the design, conduct or reporting of NSF-funded work or proposed work. This includes collaborators or consultants on any funded research or educational project. All investigators involved in a research project must become familiar with this Policy Guidance before applying for funding from NSF.

Investigators must disclose all SFI, including SFI of their spouse and dependent children. SFI include financial interests (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial concerns would reasonably appear to be affected by such activities, before funding begins.

Principal Investigators involved with research collaborators, e.g., co-investigators, sub-grantees, subcontractors or consultants, must take steps to ensure those individuals' compliance with NSF and OU requirements, and compliance with any applicable management plans established by OU.

A SFI refers to anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interest); intellectual property rights (e.g., patents, copyrights and royalties from such rights).

Investigators must disclose SFI to the AVPR or DO at the time of application for a grant and throughout the life of the grant, either updated on an annual basis or as new SFI are obtained or discovered.

SFI requiring disclosure does not include:

- Salary, royalties or other remuneration from the applicant institution;
- Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that, when aggregated for the investigator and the investigator's spouse and/or dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than 5% ownership interest in any single entity; or
- Salary, royalties or other payments that, when aggregated by the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the prior 12 month period.

Investigators must have provided all required financial disclosures at the time the proposal is submitted to NSF, on the form at the end of this guidance. This form must be hand-delivered to the ORA or emailed to FCOI@oakland.com. The financial disclosure will be reviewed by the AVPR or DO who will determine if a SFI represents a conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a SFI could directly and significantly affect the design, conduct or reporting of NSF-funded research or educational activities.

Considerations in making this determination 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 the knowledge of the investigator's FCOI. If the AVPR or DO determines that a disclosable SFI rises to the level of a SFCOI, then a management plan is necessary to manage, reduce, or eliminate such conflict of interest.

It is important for investigators to comply with these requirements for disclosure. Noncompliance 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 AVPR may designate an individual or may convene a committee to undertake retrospective reviews. Whenever OU identifies a SFI that was not disclosed in a timely manner by an investigator, or not previously reviewed by the institution, the determination of SFCOI 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 AVPR, and any reporting requirements will be met.

3. Guidelines for Management Plans

If a management plan is deemed to be necessary, the AVPR and/or DO will draft an appropriate management plan for consideration by the investigator. The investigator may request revisions to the plan before the AVPR or DO makes a final decision on the management plan. Due to the necessity to provide appropriate dispositions of FCOI's, there is no appeals process once a final decision on a management plan is made. Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include but are not limited to:

- public disclosure of significant financial interests;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;
- severance of significant financial interests or severance of relationships that create conflicts.

The Investigator must accept the management plan in writing; if the investigator does not accept the final management plan, the AVPR or DO must inform NSF's Office of the General Counsel.

The AVPR or DO is also responsible for monitoring adherence to management plans until completion of the project, which will occur annually or be done on a for-cause or random basis. NSF regulations require that the NSF Office of the General Counsel be informed if the AVPR and/or DO find that they are unable to satisfactorily manage a SFCOI.

Institutions must maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

4. Notice of NSF's Office of General Counsel for Exceptions to Management Plans

If the AVPR or DO determine that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by the interests of scientific progress, technology transfer, or the public health and welfare, the AVPR or DO may allow the research to go forward without imposing such conditions or restrictions. If the AVPR or DO finds that the conflict of interest cannot be satisfactorily managed, but that the research will proceed despite an acceptable management plan, the NSF's Office of General Counsel (OGC) will be notified within 5 business days.

In the event of an unmanageable SFCOI, OGC will be responsible for reviewing the institution's conflict of interest policy to determine if the policy addresses unmanageable conflicts. Further, OGC will be responsible for contacting the institution to determine what actions have been taken regarding the unmanageable conflict, consistent with the institution's conflict of interest policy. OGC will request confirmation from the awardee when the proposed actions have been accomplished.

SFI Disclosure Form for NSF-Funded Investigators

Investigators engaged in, or planning to engage in, NSF-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 NSF-Funded Research Project. SFIs considered to be related to the project would be those 1) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or 2) in entities whose financial interests would reasonably appear to be affected by such activities.** The requirement for disclosure of SFI meeting these criteria applies to all persons engaged in NSF-funded research activity as “investigators,” and includes (in aggregate) the financial interests of their spouse and dependent children. Principal Investigators involved with research collaborators, e.g., co-investigators, sub-grantees, subcontractors or consultants, must take steps to ensure their compliance with NSF and OU requirements, and compliance with any applicable management plans established by OU. An “Investigator” is defined as the Program Director/Principal Investigator, Co-Principal Investigator/Co-Project Director and any other person, such as the collaborators listed above, at any institution, regardless of title or position, who is responsible for the design, conduct or reporting of NSF-funded work or proposed work. **Applicable SFI’s are required to be disclosed at the following time points:**

- No later than at the time of application for NSF-funded research;
- 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.

THIS FORM NEEDS TO BE SUBMITTED TO THE OFFICE OF RESEARCH ADMINISTRATION ONLY IF AND WHEN AN INVESTIGATOR HAS A SFI TO DISCLOSE.

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 delivered to ORA or e-mailed to FCOI@oakland.edu.

Date: _____

Investigator’s name: _____

University affiliation and position: _____

Investigator’s e-mail: _____ Phone number: _____

Title of project: _____

NSF Grant Number: _____

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

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

If you are the PI, list collaborators, or “none”:

Disclosure of Significant Financial Interests (SFI)

SFI means one or more of the following financial interests (*including those of the Investigator's spouse and dependent children, in aggregate*): 1) a financial interest that reasonably appears to be affected by the research or activities funded or proposed for funding by NSF; or 2) a financial interest in entities whose financial interests would reasonably appear to be affected by such activities. Any SFI requires disclosure to the Office of Research Administration (ORA). The AVPR or DO will determine if the SFI is a financial conflict of interest exists that needs to be managed, reduced or eliminated. Answer all of the questions below for each category of SFI to determine if you have a SFI that requires disclosure. If so, complete the table and submit the SFI Disclosure Form to FCOI@oakland.edu prior to submission of your proposal to NSF.

(1) Income, including salary, royalties or other payments, from an entity that when aggregated for the investigator and the investigator's spouse and dependent children exceeds \$10,000 during the prior 12 month period. Note that salary, royalties, or other remuneration from the applicant's organization are not included in this definition. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities are also not included nor is income from service on advisory committees or review panels for public or nonprofit entities.

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) Equity interest from stocks, stock options, or other ownership interests that when aggregated for the investigator and the investigator's spouse and dependent children exceeds \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value or represents more than a 5% ownership interest in a single entity. Note that any ownership interest in the organization, if the organization is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program are not included in this definition. 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) **Intellectual property** rights and interests (e.g., patents, copyrights and royalties from such rights), upon receipt of income that exceeds \$10,000 related to such rights and interests in the previous 12 month period when aggregated for the investigator and the investigator's spouse and dependent children. Note that this does not include royalties from the applicant's organization.

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

- 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)

Table: SFI disclosures for NSF funded research

Instructions: For each category described above for which you indicated that you or your immediate family member(s) **have SFI related** to your NSF grant, 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 \$11,500 in category #1, enter this amount in the column marked "\$10,000-\$19,999"). Then provide your opinion about whether the SFI constitutes a conflict of interest (FCOI) related to the NSF-funded research project. If you need more rows for your disclosures, attach additional copies of the table.

Category	\$10,000-\$19,999	\$20,000-\$100,000	>\$100,000	Other*	FCOI Related to NSF-funded project?	
					Yes	No
1 Income						
2 Equity Interest						
3 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.

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

By signing or electronically entering my name and date in the boxes below, I attest that the information I entered above is accurate and complete to the best of my knowledge.

Name or Signature: _____ Date: _____