The Research Integrity Office within the Office of the Provost and the Office of the Vice Provost for Research (OVPR) is directly responsible for the University's Research-Related Financial Conflicts of Interest (FCOI) Program.

PHS and NSF regulations and sponsor requirements guide the University's research-related conflicts of interest policy.

FCOIs may exist when financial considerations have the potential to compromise or bias professional judgment or objectivity regarding the design, conduct or reporting of research. The University has one policy governing research-related FCOIs, the Policy on Conflicts of Interest Related to Research (the F Interest

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whether those financial hay be required to provide obligations, Investigators

prior to engaging in research at the University and at least every three years. It is the Researcher's responsibility to be aware of university and sponsor requirements and remain in compliance with them.

The Financial Conflict of Interest (FCOI) policy defines the obligations of *Investigators* in the University's research community and governs *Investigators*' financial interests / relationships related to their research, regardless of funding source. *Investigators* engaged in research are responsible for reviewing and complying with the policy prior to participating in research.

The purpose of this policy is to set forth the framework for identifying, evaluating, and managing financial conflicts of interest related to University research activities in order to

Each *Investigator* must disclose the following *Significant Financial Interests (SFIs)* (and those of his/her *Family members*) that reasonably appear to be related to the Investigator's *Institutional responsibilities:*

- X For a public *Outside organization*: remuneration for the 12 months preceding the date of the disclosure plus the value of current equity that when aggregated exceed \$5,000
- x For a non-publicly traded *Outside organizat*ion: any equity (regardless of value) and remuneration for the 12 months preceding the date of the disclosure exceeding \$5,000
- x Income from intellectual property rights not assigned to the University
- x Any *Clinical trial intellectual property*, whether or not assigned to the University
- x Any Fiduciary Role

This University policy serves as an overview of regulations. Researchers are responsible for knowing and complying with sponsor requirements. Sponsors may update or change requirements periodically. The process or procedures may then change, but the obligation to be in compliance remains unchanged. Where there are substantive differences between this policy and the regulations, the regulations take precedence.

The National Science Foundation (NSF) and the Public Health Service (PHS) require that investigators disclose to the University significant financial interests that may reasonably appear to be affected by the research being funded, i.e. where there is a risk of conflict of interest or serious appearance of conflict.

- x NSF Investigators must:
 - 1. Be familiar with the NSF Conflict of Interest policies as outlined in the PAPPG Chapter IX (<u>https://www.nsf.gov/pubs/policydocs/pappg20_1/pappg_9.jsp#IXA</u>) and other NSF standards.
 - 2. Disclose any FCOIs at the time of submission of the grant proposal and, if funded, at intervals specified by the grant.
- x PHS (NIH) Investigators must:
 - 1. Be familiar with the PHS Conflict of Interest requirements (<u>https://grants.nih.gov/grants/policy/coi/index.htm</u>)
 - 2. Complete the CITI Conflict of Interest Training and submit the certificate to the OGSP prior to proposal submission.
 - 3. Submit a Financial Interests Report Form at the time of submission of the grant proposal and, if funded, at intervals specified by the grant.
 - 4. Investigators are responsible for ensuring that subawardees contact the Office of Grants and Sponsored Programs to confirm compliance with regulations.

PHS proposals and projects have specific requirements that must be met. *Investigators* must disclose their *SFIs* 1) at the time of proposal submission; 2) annually; 3) when added as an *Investigator* to an ongoing Public Health Service (PHS) project; and 4) prior to participation in any PHS-funded research. *Investigators* are also required to timely update (within 30 days) their disclosures in the event of acquiring new *SFIs* or changes in their previously reported *SFIs*.

Investigators participating in research funded by the PHS must also disclose travel reimbursed or paid on the *Investigator's* behalf within the most recent 12 months, other than by an *Excluded Payer*.

A *financial interest* is related to an *Investigator's Institutional responsibilities* if, for example, it arises from extramural activities that derive from the *Investigator's* professional standing or are within that *Investigator*'s expertise in his or her professional field(s) of discipline, such as consulting, serving on a scientific ads ads ads ads .

respect to *Clinical Trials*, other relevant factors include the degree of risk to human subjects, the role of the *Investigator* in the study, the study's design, and the degree of the *Investigator's* influence upon the recruitment/ enrollment of subjects and/or the results of the study.

Investigators must receive training from the University programs, including the <u>CITI</u> <u>Program</u>, related to research-related *FCOI* prior to engaging in research at the University and at

Institutional responsibilities means an *Investigator*'s professional or employment-related responsibilities on behalf of the University or College, which may include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator

The term "investigator" means the PI/PD, co-PI/co-PDs, and any other person identified on the proposed project who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). "Monetary Value" shall be interpreted as anything that can be currently monetized or can reasonably be expected to result in future monetary value.

See: <u>https://www.nsf.gov/pubs/policydocs/pappg19_1/pappg_9.jsp</u>

For human subjects research, the participation of any Investigator with an FCOI is

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showF