Policy on Conflicts of Interest Related to Research (FCOI Policy)

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 FCOI Policy).

This policy is distinct from University-based annual extramural activity reporting policies and is designed to reduce, manage, and / or eliminate identified financial conflicts related to specific research projects. When required under the University's FCOI policy, disclosure of financial interests related to a specific research project should be submitted through the Financial Interest Disclosure Form. FCOI disclosures are initially reviewed by the Vice Provost for Research (VPR) and may be referred to the Deputy Provost and Provost for further review and recommendations.

Depending on the nature and value of financial interests disclosed and whether those financial interests are determined to be related to a PHS proposal, Investigators may be required to provide a more detailed disclosure. In addition to meeting the above disclosure obligations, Investigators must receive FCOI training 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.

1. Overview of Policy on Conflicts of Interest Related to Research

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.

Purpose. 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 minimize the risk of bias and to maintain integrity, credibility and respect for the work of University researchers.

Applicability. This policy is applicable to all externally-funded research being conducted under the University's auspices.

Disclosure Requirements

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:*

- 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
- 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
- Income from intellectual property rights not assigned to the University
- Any *Clinical trial intellectual property*, whether or not assigned to the University
- Any *Fiduciary Role*

PHS & NSF Disclosures

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.

- NSF Investigators must:
    1. Be familiar with the NSF Conflict of Interest policies as outlined in the PAPPG Chapter IX (https://www.nsf.gov/pubs/policydocs/pappg20_1/pappg_9.jsp#IXA) 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.
- PHS (NIH) Investigators must:
    1. Be familiar with the PHS Conflict of Interest requirements (https://grants.nih.gov/grants/policy/coi/index.htm)
    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 Pay*er.

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 advisory board, providing continuing professional education services, or serving as an expert witness for an *Outside organization* that, to the best of the *Investigator*'s knowledge, conducts or seeks to conduct business related to the *Investigator*'s field of discipline. In addition, equity in, or serving in a fiduciary role for, an *Outside organization* that, to the best of the *Investigator*'s knowledge, conducts or seeks to conduct business related to the *Investigator*'s field of discipline, is related to the *Investigator's Institutional responsibilities*.

Assessment of Disclosures. The Vice Provost for Research (VPR) will review *SFI* disclosures and the *Investigator's* assessment of the relationship of the *SFIs* to the *Investigator's* research to determine which *SFI*s (if any) are related to the research. A determination of relatedness will be made based on the *Investigator's* assessment and/or on other facts deemed relevant by the VPR. If the VPR determines that one or more disclosed *SFI*s or travel relates to the research, the VPR shall direct the *Investigator* to submit information regarding those related *SFI*s to the University's Office of the Vice Provost for Research (OVPR), using such means of disclosure as prescribed by the VPR.

Determination of a Financial Conflict of Interest (FCOI). A *Financial Conflict of Interest* (*FCOI)* is an *SFI* that could directly and significantly affect the design, conduct, or reporting of the research; and as described above in the Disclosure Requirements, and in any applicable NSF or PHS policies in force at any given time. It is the Investigator's responsibility to keep themselves informed about any changes in polices or related requirements. The University may utilize several forms of review to reasonably determine whether an *SFI* related to the research is an *FCOI,* including review by the Deputy Provost or Provost, depending on the nature and value of the disclosed financial interests, as well as other factors.

Management of FCOIs, including FCOIs Involving Clinical Trials. An *SFI* found to constitute an *FCOI* may be subject to a management plan as a condition to the *Investigator's* participation in the research. The determination of whether an *FCOI* is manageable, including an *FCOI* involving a *Clinical Trial*, should take into account relevant factors, including but not limited to, the uniqueness of the *Investigator*'s position with respect to the study, the nature and design of the research and the magnitude and nature of the *financial interest.* With

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.

Training. *Investigators* must receive training from the University programs, including the CITI Program, related to research-related *FCOI* prior to engaging in research at the University and at least every three years thereafter.

Requests from the Public Regarding FCOI Information. To the extent required by law (e.g., PHS regulations) or otherwise by the terms and conditions of a research award, in response to a written request for information related to *FCOIs* held by *senior/key personnel* of the particular research project specified in the request, the University will provide required information to the requestor.

Other Policy Provisions. The FCOI Policy encompasses other provisions as required by law, research sponsors and/or the University including the reporting of FCOIs to research sponsors (e.g., PHS agencies), as well as provisions to address noncompliance with the FCOI Policy. The FCOI disclosure and reporting requirements apply to sub-awards.

Selected Definitions

Clinical trial shall have the same meaning as prescribed from time to time by the World Health Organization.

Clinical trial intellectual property means an *Investigator*'s interest in intellectual property that is the subject of a copyright, issued patent, or a patent application (regardless of whether the intellectual property has been patented, licensed, or assigned to the University) if such intellectual property is being tested, evaluated, or developed in, or if its commercial value could be affected by, the *Clinical trial* in which the *Investigator* is engaged or proposes to engage.

Excluded payer means a Federal, state, or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Family member means an *Investigator*'s spouse or dependent child. From to time, the *Institutional official* may amend the definition of *Family member* and notify the University research community prior to the effective date of such change.

Fiduciary role means membership on the governing board of an entity, including service on its board of directors, or having a position of authority or responsibility to act in the best interest of the entity, including being an officer, manager, partner, or limited liability company member with management responsibility.

Institutional official means the Vice Provost for Research or such other person as the Provost appoints from time as the individual within the University responsible to oversee the University's compliance with conflict of interest regulations and policies.

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 means 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, whether externally or internally funded, or proposed for such funding, which may include, for example, collaborators or consultants.

Outside organization means any organization other than the University of New Haven and other than an *Excluded payer*.

2. Financial Interest Disclosure Form for Researchers

University researchers can find forms and additional information on the Office of Grants and Sponsored Programs (OGSP) web page: https://mycharger.newhaven.edu/web/mycharger/grants-and-sponsored-programs.

3. Disclosure Requirements for PHS-funded Projects

Prior to participating in research that will be funded by the Public Health Service (PHS), the University's FCOI Policy requires Investigators (the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research) to submit a Financial Interest Disclosure Form for Researchers including Significant Financial Interests and any relevant travel support. You must annually recertify the accuracy of the Financial Interests and must update your SFIs within 30 days of discovering or acquiring a new SFI not previously report.

3a) See for full details: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm

3b) Investigator Decision Tree: The Who, What, Where, and When for Disclosure Requirements
https://mycharger.newhaven.edu/web/mycharger/grants-and-sponsored-programs

4. Disclosure Requirements for NSF-funded Projects

An organizational conflict of interest policy should require that each investigator disclose to a responsible representative of the organization all significant financial interests of the investigator (including those of the investigator's spouse and dependent children): (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 interests would reasonably appear to be affected by such activities.

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: https://www.nsf.gov/pubs/policydocs/pappg19_1/pappg_9.jsp

5. FCOI Core Program Disclosure Review and Management

5a) An executed management plan is required in order for the PIs to spend awarded funds. For human subjects research, the participation of any Investigator with an FCOI is subject to the IRB's review and approval.

5b) Federal or Sponsor FCOI Reporting Requirements
OVPR staff will prepare, if applicable, *FCOI reports* required by the research sponsor or oversight agency that will contain information required by law or otherwise by the sponsor.

5c) Requests from the Public Regarding FCOI Information
To the extent required by law or otherwise by the research award, the University will make available to the public certain information regarding *FCOIs* of *Senior/Key personnel* affiliated with the University. In the case of PHS-funded research, such information shall remain available for at least three years from the date that the information was most recently updated.

6. Federal Regulations Governing FCOI (Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Protective Contractors

7. Research-related Financial Conflict of Interest (FCOI) Training

The University of New Haven subscribes to the Collaborative Institutional Training Initiative (CITI) for basic compliance training including Responsible Conduct in Research, Human Subjects Protection (IRB) and Animal Welfare (IACUC). All researchers submitting proposals to, or implementing awards from, the PHS agencies must document completion of the FCOI training module or equivalent as part of the Internal Routing Form process. Online training is supplemented with additional training opportunities.
https://about.citiprogram.org/en/homepage/

8. FDA Regulation 21 CFR Part 54
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL
PART 54 FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS
The agency reviews data generated in clinical studies to determine whether the applications are approvable under the statutory requirements. FDA may consider clinical studies inadequate and the data inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias. One potential source of bias in clinical studies is a financial interest of the clinical investigator in the outcome of the study because of the way payment is arranged (e.g., a royalty) or because the investigator has a proprietary interest in the product (e.g., a patent) or because the investigator has an equity interest in the sponsor of the covered study. This section and conforming regulations require an applicant whose submission relies in part on clinical data to disclose certain financial arrangements between sponsor(s) of the covered studies and the clinical investigators and certain interests of the clinical investigators in the product under study or in the sponsor of the covered studies. FDA will use this information, in conjunction with information about the design and purpose of the study, as well as information obtained through on-site inspections, in the agency's assessment of the reliability of the data.

APPENDICES

University Researchers: For additional information and forms go to https://mycharger.newhaven.edu/web/mycharger/grants-and-sponsored-programs.

For questions regarding FCOI, please contact Carol Withers, Director of Grants & Sponsored Programs, at 203-932-7454, cwithers@newhaven.edu or OGSP@newhaven.edu.