

Financial Conflict of Interest Standard Operating Procedure Phoenix Nest Inc.

Scope

Applies to all Phoenix Nest employees.

And all other external PI/PD's including subcontractors but excluding any federally funded institutions that are contracted by Phoenix Nest using funds from a Public Health Service (PHS) grant, except for Phase I SBIR/STTR funding.

The FCOI regulation was established to promote objectivity in research, consistent with the [Code of Federal Regulations](#) **This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.**

Purpose

To identify and manage conflicts of interest between an Investigator's research project obligations and his/her private interests or obligations.

Policy

- Federal regulations require Institutions to have policies and procedures in place to ensure that Investigators disclose any Financial Interests in relationship to Research projects funded by the United States Department of Health and Human Services (HHS), Public Health Services (PHS), and National Institutes of Health (NIH)
- All individuals listed on a protocol or grant, regardless of title or position, who may be responsible for the designing, conducting, or reporting of Research, must complete a "Financial Disclosure" form in order to disclose all Financial Interests that would reasonably appear to be related to their Institutional Responsibilities.
 - Generally, this includes all individuals listed on a grant budget, Research protocol or other Research activity. It always includes the Principal Investigator, Co-Investigators' and Key Scientific Personnel.
 - In some cases, it may include other Research personnel (such as technologists or Research fellows) if they are responsible for the design,

conduct, or reporting of the activity funded by the Research project. For the purposes of disclosure, the term “Investigator” includes the Investigator, his/her spouse or domestic partner and dependent children.

- Disclosure submitted through Research-related financial disclosure processes pertain to all Institutional Responsibilities including, Research, education, clinical practice, leadership, purchasing and administrative activities.
 - Disclosure must be made within 30 days of notice of award (NOA) and prior to approval of a Research protocol by IRB, and prior to activation of a Research project by IACUC.
 - All financial disclosures must be updated during the period of the award on an annual basis. The FCOI report shall be updated at the time of completion of the projects annual progress report. The institutions (Phoenix Nest) SO is responsible for submitting the FCOI report to the NIH.
 - During a Research project, any new Financial Interests as defined by federal regulations and Phoenix Nest, must be reported to the SO within 30 days and Managed, reduced or eliminated and reported to the PHS/NIH Awarding Component within 60 days of identification.
 - With respect to human subjects Research, the IRB has the final authority to approve the management plan developed by the Conflict of Interest Review Board prior to expenditure of an award, submission of a protocol to the IRB or activation of a Research effort within IACUC.
- 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 income, 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 or domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of fees related to such rights and interests.

Non-Compliance

If Phoenix Nest, the NIH or an external IRB finds a PI/PD SFI report to NOT be free from bias, steps will be taken to fix the PI/PD's FCOI. Some examples might be, but not limited to the following:

- Public disclosure of FCOI (e.g., when presenting or publishing the research).
- Disclosure of FCOI directly to human subjects' research participants.
- Monitoring of research by independent reviewer(s).
- Modification of the research plan.
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- Reduction or elimination of Significant Financial Interests (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts.

Definitions

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded Research.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

AOR: The Authorized Organization Representative, is the designated representative of the recipient organization in matters related to the award and administration of its NIH grants including those that require NIH approval.

Health and Human Services (HHS): The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, PHS/NIH Research funding.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflicts of Interest, which may include for example: activities such as 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 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 the PHS/NIH, or proposed for such funding, which may include, for example, collaborators or

consultants. For the purposes of disclosure, “Investigator” includes the Investigator, his/her spouse or domestic partner and dependent children.

Manage: Taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias.

Project Director (PD)/Principal Investigator (PI): A Project Director or Principal Investigator of a PHS/NIH-funded Research project; the PD/PI is included in the definitions of Senior/Key Personnel and Investigator under this subpart.

Public Health Service (PHS): The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component: The organizational unit of the PHS that funds the Research that is subject to this subpart.

Public Health Service Act (PHS Act): The statute codified at 42 U.S.C. 201 et seq.

Rebuttable Presumption: A Rebuttable Presumption is an assumption of fact accepted until disproved. All presumptions can be characterized as rebuttable. It is an assumption that is made in the law that will stand as a fact unless someone comes forward to contest it and prove otherwise. As applied to human subjects Research, the Rebuttable Presumption means that the Institution will presume, in order to ensure that all potentially problematic circumstances are reviewed, that a financially interested individual and/or institution may not conduct the human subjects Research in question.

This rule is not intended to be absolute; a financially interested individual and/or institution may rebut the presumption by demonstrating facts that, in the opinion of the Conflict-of-Interest Review Board, constitute compelling circumstances for the financially interested individual to conduct the Research in question. The individual and/or Institution would then be allowed to conduct the Research under conditions specified by the Conflict-of-Interest Review Board and approved by the Institutional Review Board.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences Research. The term encompasses basic and applied Research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which Research funding is available from a PHS/NIH Awarding Component through a grant or cooperative agreement, whether authorized under the PHS/NIH Act or other statutory authority, such as a Research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or Research resources award.

Senior/Key Personnel: The PD/PI and any other person identified as Senior/Key Personnel by the institution in the grant application, progress report, or any other report submitted to the PHS/NIH by the Institution under this subpart.

Significant Financial Interest (SFI): A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

Signing Official (SO): Person assigned the role of signing official by Phoenix Nest.

Small Business Innovation Research (SBIR) Program: The extramural Research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564

Notes

- FCOI Regulation does not apply **to:** Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Phase 1. The CRP grant is held to FCOI standards
- A FCOI must be updated and submitted to your AOR annually.
- PN's FCOI policy and procedures will be reviewed by PI/PD and any subcontractor, consultant, collaborator directly involved in the **design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements.**
- A SFI report will be made prior to PHS/NIH funding
- New SFI will be disclosed to PN within 60 days of occurrence
- Phoenix Nest employees will be required to update their FCOI training every four years.

Read and agreed by:

Name:

Date: