

Palo Alto University

Policy on INVESTIGATOR FINANCIAL CONFLICT OF INTEREST (FCOI)

I. Preamble.

All United States Public Health Service (“PHS”) agencies require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought and Responsible Prospective Contractors” issued at 42 CFR Part 50, Subpart F (the “FCOI Regulations”).

Funding from the National Institutes of Health (and other PHS agencies) represents a source, or potential source, of funding for research activities of Palo Alto University. The PHS **financial conflict of interest (FCOI)** policy has unique reporting and financial conflict of interest management requirements. This policy ensures compliance with these regulations (hereinafter, the FCOI Policy or Policy). Although designed to ensure compliance with these regulations, **all members of research study teams** are obligated to comply with the requirements of this FCOI Policy **regardless of funding source**.

The purpose of the FCOI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from the financial conflicts of interest of an Investigator. The NIH Office of Extramural Research Conflict of Interest Website contains helpful information and resources about the FCOI Regulations. See http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

The FCOI Regulations covering PHS funded activities provide for a more comprehensive level of disclosure, together with compulsory reporting to the applicable PHS agency. Disclosure to Palo Alto University is required of ALL “Significant Financial Interests” that reasonably appear related to the Investigator(s) “Institutional Responsibilities.” As more precisely defined below, “Significant Financial Interests” include all travel reimbursements of any amount, any equity interest in a privately-held entity and all other financial interests having a value in excess of \$5,000. All financial interests of a lesser amount that do not require handling under this FCOI Policy instead remain subject to disclosure and management under the general Conflicts of Interest or other appropriate Institutional policies.

For purposes of this FCOI Policy, all references to “PHS” shall be a reference to the respective PHS funding agency, including National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ). This FCOI Policy shall be made available by Palo Alto University’s Office of the Vice President for Institutional Effectiveness, Analysis, and Planning on the PAU IRB Website: <https://sites.google.com/a/paloaltou.edu/irb/>.

For purposes of this FCOI Policy, “Investigator” includes all research study team members: the Principal Investigator/Program Director, as well as all coinvestigators, collaborators, consultants, advisors, project staff and student assistants, faculty advisors and any other person, regardless of title or position, who is responsible for the design, conduct, reporting or proposing of research or other activity connected to the research study.

organization or activity.

II. Training

The Vice President for Institutional Effectiveness, Analysis, and Planning shall be responsible for ensuring that each Investigator is informed about (i) this FCOI Policy, (ii) the Investigator's responsibilities regarding disclosure of Significant Financial Interests relating to the Investigator's Institutional Responsibilities, and (iii) the FCOI Regulations. The Vice President for Institutional Effectiveness, Analysis, and Planning, who shall also serve as the **Designated Institutional Official (DIO)**, shall require each Investigator to complete training (as described below) prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every three years thereafter, and immediately when any of the following applies:

- (1) this FCOI Policy, the Financial Disclosure Form or institutional procedures are revised in any manner that affects the requirements of Investigators' reporting obligations;
- (2) an Investigator is newly appointed at Palo Alto University; or
- (3) Palo Alto University finds that an Investigator is not in compliance with this FCOI Policy or management plan.

"Immediately" shall mean the training is provided or made accessible and the Investigators participate in the training expeditiously following the event that triggers the training requirement.

At Palo Alto University, investigators who are not PHS-funded satisfy the training requirement by completing the basic COI module within the Basic Social Behavioral Research (SBR) course for human research protections that is offered by CITI. PHS-funded investigators **must** complete the CITI COI course **in addition to** the Basic SBR course.

III. Definitions

a. Financial Disclosure Form: the means by which Investigators inform the Institution of their (and their spouse or domestic partner and dependent children's) significant financial interests. These forms will be treated as confidential personnel information with all necessary precautions to protect any sensitive and/or proprietary company or sponsor information.

b. Investigator: As noted above for the purpose of this policy, investigators all persons, regardless of title or position, responsible for the design, conduct, or reporting of research.

c. Research: The Common Rule defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research...whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102(1)]

For the purposes of this policy, a "systematic investigation" is any study plan that incorporates data collection, either quantitative or qualitative, and/or data analysis to answer a study question. Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings, regardless of intent to publish the findings.

d. Significant Financial Interest (subject to the exclusions listed below):

A financial interest consisting of one or more of the following financial interests of the Investigators (and those of the Investigator's spouse and dependent children), that reasonably appears to be related to the Investigator's institutional responsibilities (see definition in 'e' below):

(i) Publicly Traded-Entities - 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.

(ii) Privately Held Entities - 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 and dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest).

(iii) Intellectual Property - Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests.

(iv) Travel Reimbursements - Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities in the twelve months preceding the disclosure; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, and 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.

The term "Significant Financial Interest" does not include:

- salary, royalties, or other remuneration paid by Palo Alto University to the Investigator if the Investigator is currently employed or otherwise appointed by Palo Alto University, including intellectual property rights assigned to Palo Alto University and agreements to share in royalties related to such rights;
- income from investment vehicles, such as mutual funds and retirement accounts, as 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; or
- income from service on advisory committees or review panels for 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.

e. Financial Conflict of Interest: A significant financial interest that is related to, and that could (or could be perceived to) directly and significantly affect the design, conduct, or reporting of research activities.

f. Institutional Responsibilities: An Investigator's professional responsibilities on behalf of Palo Alto University, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

IV. Disclosure Procedures

- a. All Investigators will submit a Financial Disclosure xForm in IRB Manager at a minimum annually (see section b). One Financial Disclosure xForm will suffice to cover all ongoing and new awards.

The lead principal investigator is responsible for ensuring compliance with this disclosure requirement by all applicable personnel.

- b. All Investigators must submit an updated Financial Disclosure xForm within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.
- c. With respect to Investigator transfers, an annual disclosure shall be made to Palo Alto University promptly to support acceptance of the appointment or employment to Palo Alto University. The reporting and management plan requirements described in Article V below shall then be required to be completed prior to expending any funds under a grant, cooperative agreement or contract.
- d. An Investigator who is new to participating in grant or contract funded activities must make sure their Financial Disclosure xForm is up to date and that required CITI training is completed to facilitate timely reporting of a FCOI (if any) to the respective funding agency.
- e. All disclosures are required to be reviewed by DIO in a prompt manner such that within sixty (60) days of receipt of the disclosure an assessment of the significant financial interest can be made, a management plan can be developed if necessary, and all the necessary reviews and approvals can be secured, such that any required report to the applicable PHS funding agency is submitted within sixty (60) days of the determination that a FCOI exists. The Investigator's timely cooperation with the efforts of the DIO is needed to ensure timely reporting. Upon a failure to make timely reporting to the PHS funding agency of a FCOI, Palo Alto University is required to, and shall, conduct a retrospective review of the Investigator's activities and the research project (See section V below)

V. Management of Financial Conflicts of Interests

- a. The DIO is responsible for assuring that all Financial Disclosure xForms are reviewed and for determining whether an Investigator's Significant Financial Interest is related to their research and, if so, whether the Significant Financial Interest is a financial conflict

of interest (FCOI). The DIO will be assisted in the initial assessment by the Human Research Protection Program Administrator and Business Office contracts and grants management personnel. The administrative personnel will assure that the DOI is made aware of all Financial Disclosures that state there is a significant financial interest that reasonably appears to have a potential conflict.

An Investigator's Significant Financial Interest becomes a financial conflict of interest (FCOI) when the DIO and/or the DIO's appointed ad hoc COI review committee reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research. For example, an Investigator (combined with the financial interests of the spouse or domestic partner, and dependent children) may be deemed to have a FCOI if, based on analysis of the scope and subject matter of the proposal, his or her Significant Financial Interest in an entity could in some way be affected by the research results from the project described in the application. In making this determination, the DIO and/or the DIO's appointed ad hoc COI review committee may consult with appropriate institutional and governmental officials.

- b.** Following determination by the DIO and/or the DIO's appointed ad hoc COI review committee that a Significant Financial Interest is an FCOI, the DIO and/or the DIO's appointed ad hoc COI review committee will then determine whether or not the FCOI can be managed, and if so, will then draft the necessary components of the management plan.
- c.** For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
 - (1) public disclosure of significant financial interests (as required by law and in any publications, presentations, or other reports generated as a result of the research);
 - (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - (3) modification of the research plan;
 - (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - (6) severance of relationships that create financial conflicts.

Additional conditions and restrictions (including a lower threshold for review) may be imposed on cases involving human subjects, as in the next section.

- d.** For research involving human subjects, the proposed management plan is forwarded to the Palo Alto University Institutional Review Board (IRB) for review.

The IRB will review the COI management plan to determine:

- Whether the COI affects the rights or welfare of research subjects,
- Whether the COI might adversely affect the integrity or credibility of the research or the research program, and
- Whether the conflict management plan effectively protects research subjects and the integrity or credibility of the research and the research program.

The IRB will also consider:

- How the research is supported or financed,
- The nature and extent of the conflict,
- The role and responsibilities of the conflicted individual in the design, conduct, and reporting of the research, and
- The ability of the conflicted individual to influence the outcome of the research.

The IRB has final authority to determine whether the research, the COI (financial or otherwise) and the conflict management plan, if any, allow the research to be approved. With regard to any conflict management plan issued by the DIO and/or the DIO's appointed ad hoc COI review committee, the IRB shall either affirm or strengthen it. The IRB can require additional measures to manage a COI so that the research may be approved. However, the IRB cannot weaken a conflict management plan approved by the DIO and/or the DIO's appointed ad hoc COI review committee.

For example, in addition to any conflict management plan, the IRB may require:

1. Disclosure of the COI to subjects through the consent process
2. Modification of the research plan or safety monitoring plan
3. Monitoring of research by a third party
4. Disqualification of the conflicted party from participation in all or a portion of the research
5. Appointment of a non-conflicted PI
6. Divestiture of significant financial interests
7. Severance of relationships that create actual or potential conflicts.

In the event the conflict cannot be effectively managed, the IRB may disapprove the research.

- e. For all management plans, the DIO and/or the DIO's appointed ad hoc COI review committee will monitor Investigator compliance with the management plan on an on-going basis until the completion of the funded research project.

VI. Reporting Financial Conflicts of Interests to PHS

- a. Prior to expending any funds under an PHS funded grant, cooperative agreement or contract, Palo Alto University must report to the applicable PHS funding agency the existence of any FCOI (as defined in Section IV above) and assure that it has implemented a management plan in accordance with the FCOI Regulations as discussed in IV above. If Palo Alto University identifies a FCOI and eliminates it prior to the expenditure of any PHS- awarded funds, the Institution is not required to submit a FCOI report to the respective agency.
- b. For any FCOI reported to the respective agency relating to an on-going PHS-funded research project, an annual report that conforms to the requirements of the PHS COI regulations shall be made to the applicable funding agency by the DIO and/or the DIO's appointed ad hoc COI review committee for the duration of the research project in the time and manner specified by the applicable funding agency.
- c. For any Significant Financial Interest that Palo Alto University identifies as being a FCOI subsequent to Palo Alto University's initial FCOI report under the award, the report will be made to the applicable funding agency and a management plan shall be implemented within sixty (60) days of that identification. Such a disclosure could include a new

Significant Financial Interest received by the Investigator during the on-going research project, or a Significant Financial Interest held by an Investigator who is new to the research project. However, if that FCOI is one that was not timely made to the applicable funding agency, for whatever reason, Palo Alto University is required under the FCOI Regulations to conduct a retrospective review of the Investigator's activities and the research project within 120 days of the Institution's determination of non-compliance. If bias is found during the course of this review, a mitigation report will also be required to be submitted. These reviews and reports must be documented in accordance with the requirements of the PHS COI regulations.

- d. The elements of such a report shall include, at least, the items enumerated under the PHS COI regulations. The PHS COI regulations provide that, to the extent permitted by law, the Government will maintain the confidentiality of all records of financial interests.
- e. Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the Institution, through DIO and/or the DIO's appointed ad hoc COI review committee, shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning a Significant Financial Interest which was disclosed and is still held by key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be a FCOI. The information shall consist of the information required to be provided under the PHS COI regulations.

VII. Sub-recipient Compliance and Reporting

- a. All proposed sub-recipients under a PHS-funded research of Palo Alto University shall conform to the requirements of the PHS COI regulations and this policy. With respect to these sub-grantees, subcontractors, and collaborators, Palo Alto University must require these entities to enter into a written agreement and make a certification to Palo Alto University at the time of award that its financial conflicts of interest policy complies with the PHS COI regulations. The written agreement shall include all of the terms required under the PHS COI regulations.
- b. Palo Alto University, through the DIO and/or the DIO's appointed ad hoc COI review committee, will report to the PHS funding agency any FCOI which are identified by any sub-grantee, subcontractor, or collaborator to Palo Alto University in the manner required under the PHS COI regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

VIII. Remedies

- a. If an Investigator fails to comply with this Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS-funded research, Palo Alto University, through its DIO and/or the DIO's appointed ad hoc COI review committee, as required under the PHS COI regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, the DIO and/or the DIO's appointed ad hoc COI review committee shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the PHS COI regulations. The agency may take its own action as it deems appropriate, which may include

suspension of funding, or require the Institution to take further action to maintain the objectivity of the research.

- b. For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, Palo Alto University, through its DIO and/or the DIO's appointed ad hoc COI review committee, must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

IX. Violations, Sanctions, and Appeals

- a. All persons subject to this Policy are expected to comply with it fully and promptly. Whenever an Investigator has violated this Policy, for example by a failure to disclose a conflict, financial or otherwise, the DIO and/or the DIO's appointed ad hoc COI review committee may refer the matter to another appropriate organizational official or committee for disciplinary action or other appropriate action.
- b. Violations of this Policy and the FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with any respective organizational policy and procedures governing allegations of research misconduct.

X. Records

Palo Alto University, through the DIO, is required pursuant to the PHS COI regulations to maintain all Financial Disclosure Forms and all related records of actions taken by the Palo Alto University with respect to disclosures of financial interests (whether or not a disclosure resulted in its determination of FCOI) for a period of three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

XI. Non-Funded Research

For all other non-funded research, research shall not begin unless the DIO has determined that no FCOI exists, or that any identified FCOI is managed under the terms of a management plan that has been both adopted and implemented.