

Financial Conflict Of Interest Policy for Public Health Service Funding (in accordance with 42 CFR Part 50- Subpart F, and 45 CFR Part 94)

I. PURPOSE & SCOPE

The federal Public Health Service (PHS) has adopted regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on *Promoting Objectivity in Research*. These regulations describe the actions the Principal Investigators and all other Investigators (regardless of position or title) and their organizations must take in order to promote objectivity in research. The regulations apply to all applications as prime awardee or subawardee for PHS funding and to all PHS funded grants, cooperative agreements, research contracts, and subawards where the originating sponsor is PHS.

II. KEY DEFINITIONS

PHS means the Public Health Service of the United States 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).

Investigator is defined as 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 directly as prime awardee or indirectly as subawardee by the PHS, or proposed for such funding, which may include, subgrantees, contractors, consortium participants, collaborators or consultants. To ensure personnel are correctly identified for the purpose of Policy compliance, consider the role of those involved rather than their title and the degree of independence with which they work.

Institutional Responsibilities are defined as an Investigator's professional responsibilities on behalf of his/her institution, e.g. research, research consultancy, teaching, professional practice, University committee memberships, service on panels such as ethical review boards.

A **Significant Financial Interest (SFI)** exists when a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities on behalf of his/her institution:

- a) **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 for the investigator, investigator's spouse and dependent children, 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;

- b) **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 dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- c) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.
- d) **Third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children and not reimbursed to the Investigator and/or the Investigator's spouse/dependent children so that the exact monetary value may not be readily available) of greater than \$5,000 that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, research, or clinical activities) must be disclosed to the institution. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement excludes travel paid for by the institution and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, an U.S. 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 the following types of financial interests:

- a) Salary, royalties, or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by that institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights;
- b) 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;
- c) Income from seminars, lectures, or teaching engagements sponsored by an U.S. 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
- d) Income from service on advisory committees or review panels for an U.S. 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.

A **Financial Conflict of Interest (FCOI)** exists when the institution, through its Designated Officials, that for the Università degli Studi di Padova are represented by the Heads of Departments (HoD), reasonably determine that an Investigator's SFI is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

III. KEY STAFF INVOLVED

Key staff required to administer the Policy are:

- a) All Investigators;
- b) Each Investigator's Head of Department (HoD);
- c) Departmental administrative staff;
- d) The Rector;
- e) The International Research Office.

IV. DISCLOSURES

Each Investigator must disclose to his/her HoD any SFI (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. Disclosures must be made using the disclosure form prior to applying for PHS funded research, within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI and at least annually during the period of the award. Such disclosure must include any information that was not disclosed initially to the institution, pursuant to this Policy, or in a subsequent disclosure of SFI, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Any new Investigator, who, subsequent to the submission of an application to PHS for funding, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to his/her HoD promptly and prior to participation in the project.

Each Investigator who is participating in research under a subaward where the prime award originates from PHS must submit a disclosure of SFI prior to the submission of the application, within (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI and at least annually, during the period of the award.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward are expected to comply with the policies and procedures of the organization at which they are employed.

Subrecipients who do not have a FCOI policy that conforms to 45 CFR Part 94 and 42 CFR Part 50, Subpart F shall agree to rely on the Università degli Studi di Padova's FCOI policy and procedures to comply with PHS Conflict of Interest regulations.

Subawards issued by the Università degli Studi di Padova will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOIs are identified, for sending to the Università degli Studi di Padova a notification of their ability to manage the identified conflicts, in accordance with PHS reporting requirements, within 45 (forty-five) days from the determination of the FCOI.

V. REVIEWS

The HoD represents the Università degli Studi di Padova's designated official who will conduct reviews of disclosures. The HoD will review any SFI that has been identified in a disclosure; these interests will be compared to each research award or subaward funded by PHS on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award or subaward and, if so, whether the SFI creates an FCOI related to that research award or subaward.

An Investigator's SFI is related to the PHS-funded research when the HoD reasonably determines that the SFI: could be affected by the research; or is in an entity whose financial interest could be affected by the research. The HoD may involve the Investigator in the determination of whether a SFI is related to the PHS-funded research.

An FCOI exists when the HoD reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In determining if an Investigator's SFI is related to the PHS-funded research, and if so, whether the relationship creates an FCOI, the HoD considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity.

VI. MANAGEMENT OF SIGNIFICANT FINANCIAL INTERESTS THAT POSE FINANCIAL CONFLICT(S) OF INTEREST

If an FCOI exists, the HoD together with the Rector will develop a management plan, determining by what means the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the HoD and the Rector will be guided by the principles discussed in this Policy. The HoD and the Rector will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage an FCOI include, but are not limited to:

- a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
- c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- d) Modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- g) Severance of relationships that create financial conflicts.

The management plan should also include the following details:

- a. The role and principal duties of the conflicted Investigator in the research project;
- b. Conditions of the management plan;

- c. How the management plan is designed to safeguard objectivity in the research project;
- d. Confirmation of the Investigator's agreement to the management plan;
- e. How the management plan will be monitored to ensure Investigator compliance; and
- f. Other information as needed.

The determination of the HoD about the existence of an FCOI and the means he/she and the Rector has identified for eliminating or managing the conflict, will be communicated in writing to the relevant Investigator. The departmental administrative staff of the Investigator's department will keep a record of Investigator disclosures of SFI, the HoD's review of, and response to, such disclosure and all actions under this Policy. Such records will be maintained and kept for at least 3 (three) years from the date the final expenditures report is submitted and in accordance with the relevant PHS Regulations. If the HoD prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on the project supported directly by PHS will be permitted until the Investigator has complied with the disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the HoD and the Rector necessary to manage the FCOI. The Investigator cannot incur expenditures until the PHS has received the FCOI Report and has sent notification to the Investigator to do so.

No expenditures on a subaward supported by a PHS prime award will be permitted until the Investigator has complied with the disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the HoD necessary to manage the FCOI. The HoD will communicate, in writing, with the PHS prime awardee to notify it of the existence and the nature of an FCOI and whether the conflict has been managed, reduced, or eliminated. The Investigator cannot incur expenditures until the PHS prime awardee has reported the FCOI to PHS and has received notification from the PHS to do so.

The Università degli Studi di Padova's subawardees cannot incur in any expenditures on their subaward supported by PHS until the subaward Investigator has complied with the disclosure requirements of the FCOI Policy of their institution, or this Policy, and has agreed, in writing, to comply with any plans determined necessary to manage the FCOI. The subawardee institution will communicate, in writing, with the Università degli Studi di Padova to notify it of the existence and the nature of an FCOI and whether the conflict has been managed, reduced, or eliminated. The subaward Investigator cannot incur expenditures until the Università degli Studi di Padova has reported the FCOI to PHS and has received notification from the PHS to do so.

VII. REPORTING

If the HoD has determined that an FCOI exists and prior to the expenditure of any funds under an award or subaward funded by PHS by the Investigator, the Università degli Studi di Padova will submit to the PHS or to the prime awardee an FCOI report compliant with PHS regulations regarding any Investigator's SFI found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan.

In the case the investigator is a NIH grantee, this will be via the electronic Research Administration (eRA) Commons FCOI Module. The HoD and the Rector are responsible for ensuring that reports are submitted on time via the International Research Office as and when required. The Head of the International Research Office has authorized access to submit forms through the eRA Commons FCOI Module.

While the award or subaward is ongoing (including any extensions with or without funds), the Università degli Studi di Padova will provide to PHS or PHS prime awardee an annual FCOI report that addresses the status of the FCOI (i.e. whether the financial conflict is still being managed or an explanation of why the financial conflict no longer exists) and a description of any changes in the management plan since the last FCOI report was submitted.

For any SFI that is identified as conflicting subsequent to an initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project or the investigator's new SFI that is deemed to be an FCOI), the Università degli Studi di Padova will provide to PHS within 60 (sixty) days or the PHS prime awardee within 45 (fourty-five) days, an FCOI report regarding the FCOI and ensure that it has implemented a management plan and the Investigator has agreed to the relevant management plan.

All FCOI reports must include sufficient information to enable PHS to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The regulation provides key elements that must be included in the FCOI report. These include but are not necessarily limited to the following:

- a) Grant Number;
- b) Name of Investigator with FCOI;
- c) Subrecipient Report or not;
- d) Project Title, Project Period, Budget;
- e) Name of the entity with which the Investigator has an FCOI;
- f) Nature of the SFI (e.g., equity interest, intellectual property rights not from the awardee institution, investment vehicles, such as mutual funds and retirement accounts, controlled by the investigator, payment for services such as consulting fees, honoraria, paid authorship, reimbursed or sponsored travel, salary not from the awardee Institution, other);
- g) Value of the SFI (the choices in value ranges from \$0 to \$599,999, >\$600,000, or a statement that the interest is one who value cannot be readily determined through reference to public prices or other reasonable measures of fair market value);
- h) A description of how the SFI relates to the PHS funded research and how it conflicts with such research;
- i) Non compliance instructions.

In cases in which the Università degli Studi di Padova identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, an FCOI report shall not be submitted.

The Institution must submit a new FCOI report if any of the following elements of a previously submitted FCOI report changes:

- a) Project Number;
- b) Name of Investigator with the FCOI;
- c) Name of the entity;
- d) Nature of the SFI.

If the value of a reported SFI changes during the year, the Investigator should disclose the change to the Università degli Studi di Padova in his/her annual disclosure. Changes in the value of an SFI do not constitute a “new” FCOI report. The annual FCOI report will provide the status of the existing FCOI and any changes to the management plan that may result due to the increase in value.

VIII. NON COMPLIANCE

When an FCOI is not identified or managed in a timely manner, including, for example, because the underlying SFI is not disclosed timely by an Investigator or, because an FCOI was not timely reviewed or reported by a subawardees or by the Università degli Studi di Padova; or because an investigator failed to comply with a management plan; then the Università degli Studi di Padova will:

- a) Complete a retrospective review of the Investigator’s activities and the research project to determine any bias in the design, conduct or reporting of research;
- b) Document the retrospective review consistent with the regulation; and
- c) Document its determination as to whether any PHS funded research, or portion thereof, conducted during the period of time of the Investigator’s non-compliance with the FCOI Policy or an FCOI management plan, was biased in the design, conduct, or reporting of such research;
- d) Submit the retrospective review to PHS within 120 (one hundred and twenty) days or to PHS awardee within 90 (ninety) days if no bias are found. The retrospective review must include at least the following key elements:
 - a) Project number;
 - b) Project title;
 - c) PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - d) Name of the Investigator with the FCOI;
 - e) Name of the entity with which the Investigator has an FCOI;
 - f) Reason(s) for the retrospective review;
 - g) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
 - h) Findings of the review; and
 - i) Conclusions of the review.
- e) If bias are found, complete and submit promptly a mitigation report describing the impact of the bias on the research project and the plan of actions taken to eliminate or mitigate the effect of the bias to PHS or PHS prime awardee. If the FCOI was previously reported to PHS or

PHS prime awardee, the mitigation report is submitted as a “Revised FCOI Report.” The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Subawardees of the Università degli Studi di Padova must send their retrospective review to the Università degli Studi di Padova within 90 (ninety) days and if bias are found they must complete and submit promptly a mitigation report describing the impact of the bias on the research project and the plan of actions taken to eliminate or mitigate the effect of the bias.

Thereafter, the Università degli Studi di Padova shall submit FCOI reports annually to PHS or PHS prime awardee, in accordance with the regulation.

IX. RESPONSIBILITIES OF THE UNIVERSITÀ DEGLI STUDI DI PADOVA FOR SUBRECIPIENTS

The Università degli Studi di Padova is responsible for ensuring any subrecipient’s compliance with the regulation and reporting identified FCOI for subrecipient Investigators to PHS. The Università degli Studi di Padova must incorporate as part of a written agreement with a subrecipient terms that establish whether its FCOI Policy or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

The Università degli Studi di Padova is responsible for monitoring subrecipient’s compliance with the FCOI regulation, management plans, and for reporting all identified FCOI to PHS.

X. REQUIREMENTS FOR MAKING INFORMATION ON FCOI POLICY and FCOI PUBLICLY ACCESSIBLE

The Università degli Studi di Padova shall ensure public accessibility to its FCOI policy via its publicly accessible Web site.

Prior to any expenditure of any funds under a PHS-funded research project, the Università degli Studi di Padova shall ensure public accessibility, via written response within 5 (five) business days of a request, of information concerning any SFI disclosed that meets the following three criteria:

- a) The SFI was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified in the grant application, progress report, or any other required report submitted to PHS;
- b) HoD has determined that the SFI is related to the PHS-funded research; and
- c) HoD has determined that the SFI is an FCOI.

The Università degli Studi di Padova shall ensure public accessibility, via written response, at a minimum, the following:

- a) Investigator’s name;

- b) Investigator's title and role with respect to the research project;
- c) Name of the entity in which the SFI Interest is held;
- d) Nature of the SFI; and
- e) Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

XI. CLINICAL RESEARCH

In any case in which PHS or PHS prime awardee determines that a funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not managed or reported by the Università degli Studi di Padova as required by the regulation, the Università degli Studi di Padova requires the Investigator(s) involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

XII. TRAINING REQUIREMENTS

Each Investigator, including sub-recipient Investigator(s), must complete training prior to engaging in research related to any PHS-funded award or subaward and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

- a) the Università degli Studi di Padova revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
- b) An Investigator is new to the Università degli Studi di Padova research under an award or subaward issued by PHS (training is to be completed prior to his/her participation in the research);
- c) the Università degli Studi di Padova finds that an Investigator is not in compliance with this Policy or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the HoD).

In fulfillment of the training requirement, the Università degli Studi di Padova requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html in accordance with the requirements and expectations of this Policy as well as to read the information provided on the International Research Office web pages of the Università degli Studi di Padova's web site. All investigators must print a certification of completion at the end of training and retain it for audit purposes.