

CONFLICT OF INTEREST IN RESEARCH: GUIDELINES AND PROCEDURES

Responsible Office: Grants and Sponsored Projects

Effective Date: August 24, 2012

Responsible Official: University Director, Grants and Sponsored Projects Last Revision: November 17, 2020

I. Policy Statement

Fairleigh Dickinson University (“University”) is committed to preserving the public trust, and upholding the integrity of its faculty, staff, students and affiliates in the design, conduct and reporting of **research**. This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under **Public Health Service (PHS)** sponsored grants or cooperative agreements will be free from bias resulting from investigator **Financial Conflict of Interest**.

University faculty and other research personnel, or “**investigators**” may have relationships with entities outside of the University that reasonably appear to be related to their **PHS sponsored grants**. In accordance with Public Health Service (PHS) [Policy 42 CFR Part 50 Subpart F \(“regulations”\)](#) an investigator’s **Significant Financial Interests (SFI)** must be disclosed to the University. If the nature of the SFI is determined to be a Financial Conflict of Interest (FCOI), i.e. affects (or is perceived to affect) the design, reporting and conduct of PHS sponsored research, the University is required to identify, manage, reduce or eliminate the real or perceived financial conflict of interest in a timely manner, *consistent with Section IV*. These guidelines are **specific to the conduct of PHS supported research related to the Investigator’s responsibilities**, and mandated since federal requirements are not identical to the financial disclosure obligations required under the University’s existing policies on *Conflicts of Interest and Nepotism* and *Code of Conduct and Ethics*. Compliance with this Conflict of Interest in Research policy will not relieve faculty, other research personnel, or investigators of their respective obligation to comply with the aforementioned policies.

II. Definitions

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

Equity interest means any stock, stock option, or otherwise ownership interest as determined through reference to public prices, or other reasonable measures of fair market value.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct and reporting of the research.

- **Financial Conflict of Interest**, governed under this policy, exists when the University, through its designated official(s), reasonably determines that an investigator’s significant financial interest is related to a PHS funded research project and could directly and significantly affect the design, conduct, or the reporting of research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives PHS research funding.

Institutional Responsibilities means an investigator's professional responsibilities on behalf of the institution, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review and Data Safety Monitoring Boards.

Intellectual Property Rights and Interests means receipt of income related to such rights and interests by the investigator and/or the investigator's spouse and dependents. (e.g., patents, copyrights, trademarks, trade secrets).

Investigator means the project director, principal investigator, or any other person regardless of title or position who is responsible for the design, conduct or reporting of research funded by PHS, or proposed for such funding, which may include collaborators or consultants.

Public Health Service means 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 NIH.

Remuneration includes salary, and any payment for services otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Research means 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.

Senior/Key Personnel means the Project Director/Principal Investigator (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 by the Institution under the regulations.

Significant Financial Interest (SFI) means **remuneration; financial interest; equity interests; intellectual property rights and interests** (e.g., patents, copyrights and royalties from such rights) reasonably related to the individual's institutional responsibilities, e.g., research and/or scholarly activities, teaching and advising.

- **Publicly Traded Entities**-A SFI exists if the value of remuneration received by the investigator (and/or his/her spouse and dependents) by the entity, in the previous 12 months preceding the disclosure, and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000.
- **Non-Publicly Traded Entities**-A SFI exists if the value of any remuneration received by the investigator (and/or his/her spouse and dependents) in the preceding 12 months, exceeds \$5,000, or when the investigator (and/or the investigator's spouse and dependents) holds *any* equity interest in the entity.
- **Intellectual Property Rights and Interests (e.g., patents, copyrights)**-A SFI exists upon receipt of income related to such rights and interests by the investigator and/or the investigator's spouse and dependents.

Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to PHS sponsored research (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) by an outside entity *other than* the University, and other than that reimbursed or sponsored by a federal, state, or local government agency, or an institution of higher education.

A Significant Financial Interest becomes a Financial Conflict of Interest if it could result in personal gain, advantage to others to the detriment of the University, or influence the design, conduct and reporting of the investigator's PHS sponsored research.

The term SFI does not include:

- salary, royalties or other remuneration from the University;
- income from service on advisory committees or review panels for public or nonprofit entities;
- royalties or other payments from publicly traded entities, when aggregated for the investigator, and the investigator's family, are not expected to exceed \$5,000 during the previous twelve-month period;
- income from self-authored textbooks, software, etc. that are used for your teaching purposes;
- travel related or sponsored travel related to institutional responsibilities that is reimbursed by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a) (see additional information in III. Procedures. v. PHS-funded Travel Reporting Requirements ;
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control decisions made on the investment vehicles;
- income from seminars, lectures or teaching engagements sponsored by and service on an advisory or review panel for federal, state, or local government agency, or other institution of higher education.

III. Procedures

Investigator Disclosure

As required under PHS policy, all investigators involved in the design, conduct, and reporting of research (“Key Personnel”) must disclose any significant financial interests that reasonably appear to be related to his/her institutional responsibilities as related to the **PHS sponsored research**. SFIs will be disclosed by Key Personnel using the Significant Financial Interests Disclosure Form at the time of PHS submission, at time of funding acquisition, annually thereafter, and during the funding period. New PHS funded faculty must disclose within 60 days of appointment. The investigator shall, to the best of his/her knowledge, disclose personal significant financial interests as well as significant financial interests of his/her spouse and dependents that reasonably appear to be related to the investigator’s institutional responsibilities as related to the PHS sponsored research. The SFI Disclosures will be retained by the GSP office in a central repository and remain on file for a period of three years beyond the date of initial disclosure or three years following the conclusion of the PHS project period.

The GSP will provide the following documentation to all Key Personnel prior to the required disclosure periods: (1) the Conflict of Research: Guidelines and Procedures Policy; (2) link to the federal regulations of 42 CFR 50; (3) Investigator’s disclosure responsibilities procedure with the Significant Financial Interest (SFI) Disclosure form and (4) training requirements in responsible conduct of research and financial conflict of interest.

An FCOI exists “when the Institution, through its designated official(s), reasonably determines 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”.

- i. Significant Financial Interest Disclosure for Individual PHS Proposal Submissions:** The University’s proposal submission procedures require the Principal Investigator/Project Director to complete and submit to the GSP a Proposal Development Authorization (PDA) form prior to each proposal submission, designating the date of SFI disclosure. The PDA is reviewed and endorsed by all key personnel, Department Chairs, Deans, University Provost, and the GSP University Director prior to submission.

In accordance with PHS policy, all University investigators who apply for PHS sponsored funding must complete a Significant Financial Interest Disclosure Form in compliance with 42 CFR 50 Subpart F prior to submission.. If no SFI is disclosed, no further review is required and no additional action will be required of any investigator unless the proposal is awarded, or a change occurs prior to the next annual award date. If a SFI is disclosed, the GSP office will gather additional information and supporting documentation *as needed* from the investigator and route all potential conflicts to the General Counsel and University Provost for subsequent review. The Procedures for Review and Management (see Section IV) will be followed if any SFI is reasonably determined to be a real or perceived financial conflict of interest related to the PHS sponsored research that could directly and significantly affect the design, conduct or reporting of the research.

ii. Significant Financial Interest Disclosure – Ongoing Requirements: In accordance with PHS policy, all University investigators who receive PHS sponsored funding must complete a Significant Financial Interest Disclosure Form in compliance with 42 CFR 50 Subpart F. The SFI form must be completed and returned to the GSP office within 30 days of the time of initial funding, acquisition of a new significant financial interest, and annually thereafter during the funding period. All investigators with PHS sponsored research and new to the University must provide a SFI Disclosure within 60 days of appointment to the University. Upon receipt of each initial, annual or updated disclosure form, the University Director of GSP will review the disclosure, requesting additional information, as necessary. If no significant financial interests related to Investigator’s institutional responsibilities related to the PHS funded research are disclosed, no further review is required and no additional action will be required of the investigator unless a significant change in status occurs prior to the next annual due date. Investigators will be reminded of this requirement electronically when the GSP Director’s signed Disclosure form is sent back to the Investigators for his/her records. If an SFI is disclosed by any investigator at the time of award, the GSP office will gather additional information and supporting documentation as needed from the investigator and route all potential conflicts to the General Counsel and University Provost for subsequent review. The Procedures for Review and Management (see Section IV) will be followed if any SFI is reasonably determined to be a real or perceived financial conflict of interest related to the PHS Sponsored Research that could directly and significantly affect the design, conduct or reporting of the research.

Human Subjects Research/IRB Submissions: In addition to the above, all Investigators are required to report if he/she may have a financial interest in his/her human subjects research by disclosing in the IRB’s New Project Application. The IRB will review all information to ensure the protection of human subjects. If a financial conflict of interest exists and the project is greater than minimal risk, a copy of the Significant Financial Interests Disclosure Form required under this Policy must be provided along with the IRB submission. Please see Section IV. Review and Management of SFI for further information on review and additional requirements.

iii. Change in Significant Financial Interest Status: Key Personnel will be reminded by the GSP at the time of application, funding assignment and annually thereafter, that should a new reportable significant financial interest arise (e.g. through purchase, marriage or inheritance) for any investigator during the period of grant funding, an updated SFI Disclosure form must be submitted to the GSP within 30 days of discovering or acquiring a new Significant Financial Interest of themselves or of family members.

IV. Review and Management of SFI associated with a PHS award

A. Management of Financial Conflicts of Interest

Should a Significant Financial Interest Disclosure related to PHS sponsored research indicate a real or perceived financial conflict of interest, the University Director of GSP will gather additional information and supporting documentation *as needed* from the investigator and route all potential conflicts to the General Counsel and University Provost for subsequent review.

Should initial findings indicate the existence of a financial conflict of interest, the General Counsel shall call a special meeting of the Financial Conflict of Interest Management Committee, i.e., *Management Committee*. The Management Committee shall be comprised of no fewer than two faculty members, appointed by the University Provost and the University Director of the GSP. The University General Counsel shall be a non-voting member of the Management Committee. The Management Committee will review the documentation, and provide the investigator an opportunity to meet with the members of the Management Committee to explain the financial documentation and FCOI. The Management Committee, with all due considerations, will recommend actions to the University Provost to effectively mitigate, manage, reduce, or eliminate the conflict. If the University is unable to manage or eliminate the FCOI prior to the expenditure of PHS awarded funds, the University shall provide to the PHS awarding component an FCOI Report regarding any SFI found to be conflicting, and ensure that the University has implemented a management plan in accordance with 42 CFR 50.605. The SFI Disclosures will be retained by the GSP office in a central repository and remain on file for a period of three years beyond the date of initial disclosure or three years following the conclusion of the PHS project period.

If the research involves human subjects and is greater than minimal risk, the approved conflict management and/or mitigation plan will be communicated to the IRB. If the conflict management and/or mitigation plan permits the research to proceed, such plan will provide, at a minimum, for appropriate disclosure to human subjects involved in the research study, if any, and to the public in presentation and publications of resulting research data.

Examples of conditions or restrictions that might be imposed to manage an investigator's financial conflict of interest (if any) include, but are not limited to the following:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to University's Institutional Review Board(s);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts of interest.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project involving clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, that has been designed, conducted, or reported by an Investigator with an FCOI that was not managed

or reported by the Institution as required by the regulations, the Institution shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research, and
- Request an addendum to previously published presentations.

B. Appeal Process

Should the faculty member or other investigator not agree with the Financial Conflict of Interest Management Committee's conditions or restrictions, he/she can appeal in writing to the Provost within ten (10) days after receipt of notification from the Management Committee spelling out why such conditions and restrictions are inappropriate. The Provost and/or his/her designee will then consult with the Financial Conflict of Interest Management Committee; it is possible that a modification of the conditions and restrictions will be agreeable to all parties. However, the decision of the Provost and/or his/her designee is final.

C. Non-Compliance

Non-compliance occurs when an investigator does not disclose in a timely manner an SFI that is determined to be an FCOI; the Institution fails to review or manage such a FCOI; or the investigator fails to comply with the management plan of a FCOI relative to a PHS funded research project. Such cases of non-compliance must be promptly reported to the PHS funding agency.

When a previously existing significant financial interest is not managed in accordance with its management plan or the University fails to review a previously existing significant financial interest during an ongoing PHS funded project, the University is required to perform a review of the significant financial interest and reasonably determine if a real or perceived financial conflict of interest exists that is related to a PHS funded research project and if the interest could significantly affect the design, conduct or reporting of the research. If a FCOI is identified, the University must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be taken to manage such financial conflict of interest going forward, and submit an FCOI report to PHS. When a matter of non-compliance is identified, the FCOI Management Committee must conduct a review within 60 days of the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists and if so: implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be taken to manage such conflict of interest going forward.

In addition to the FCOI report, the University must, within 120 days of its determination of noncompliance, complete a **retrospective review** of the investigator's research activities and the PHS funded research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, and specify the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found, the appropriate PHS sponsoring agency will be notified promptly and mitigation report submitted that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter, the University will submit FCOI reports annually specifying whether the Financial Conflict of

Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. . The University is required to document the Retrospective Review through a national database, which may be discoverable via the Freedom of Information Act.

V. Institutional Compliance and Reporting Responsibilities

A. Prior to Award

Prior to spending any funds under an award, the Institution must report to the PHS sponsoring agency the existence of any conflicting financial interests and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations. The Institution must also provide an FCOI report whenever an investigator does not timely disclose a Significant Financial Interest or whenever the Institution, for whatever reason, does not review a disclosed Significant Financial Interest and the Institution then determines that a Financial Conflict of Interest exists.

B. Ongoing Projects

The Institution must submit an FCOI report to the PHS awarding component within sixty (60) days after its determination that an FCOI exists for an investigator who is newly participating in the project or for an existing investigator who discloses a new Significant Financial Interest to the Institution during the period of award.

C. Annual FCOI Report

For any Financial Conflict of Interest previously reported by the Institution, the Institution shall provide an annual FCOI report to the appropriate PHS Agency, e.g., NIH that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. Annual FCOI reports must be submitted to the PHS awarding component for the duration of the project period (including extensions with or without funds) at the same time the Institution is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable). When a conflicting financial interest ceases to exist during the ongoing project period, the Institution should update the status of the Financial Conflict of Interest at the time of the next annual FCOI report submission deadline.

D. Subrecipients

The awardee institution is responsible for ensuring any subrecipient's compliance with the regulations and reporting of identified financial conflicts of interests for subrecipient investigators to the PHS awarding component, if required under the terms and conditions of the sponsored research project.

The GSP office will obtain a certification from the subrecipient that its FCOI policy and management practices comply with the regulations. The University shall incorporate and establish, as part of the written terms of the subaward agreement, that the Subrecipient and its investigators shall remain compliant with the subrecipient's FCOI Policy and the regulations.

Alternatively, the University shall incorporate and establish, as part of the written terms of the subaward agreement, that the Subrecipient shall report identified FCOIs for its Investigators in a time frame that allows the University to report identified FCOIs to the PHS agency as required by the regulations, or otherwise include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the University to identify, manage and report identified FCOIs to the agency.

E. Reporting Requirements for SFIs that are determined to be FCOIs

All FCOIs must be reported through the federally managed Electronic Research Administration (eRA) Commons web-based system. The University is required to make a public disclosure of such information including but not limited to the name of the investigator, the conflicted company, and the amount of the financial interest either through a website or by written request within 5 days of the request. The University will respond in writing on a case-by-case basis to requests for this information **and will not maintain a website to report such interests**. Affected faculty will be notified in advance of the release of this information in response to any such request.

VI. Training Requirements

Institutional Resources: Fairleigh Dickinson University will provide FCOI training to key personnel identified on federally funded research. The University utilizes the Collaborative Institutional Training Initiative (CITI), a web-based module for Research Conflict of Interest (COI) training, in order to comply with this requirement. In addition to Key Personnel, the PIs must notify the GSP office if there are others working on any PHS-funded research projects, regardless of title or position, responsible for the design, conduct, or reporting of the research that will include post-doctoral fellows, students, professional research staff, collaborators or consultants. All such personnel will also be required to complete the training.

Investigator Requirements: The PHS revised regulations on FCOI requires that each investigator (Principal Investigators (PIs) and Independent Investigators), and key personnel described on the award application must complete training prior to engaging in research related to any PHS funded grant, at least every four (4) years thereafter, and immediately under the following designated circumstances:

1. University FCOI Policy changes in a manner that affects investigator requirement
2. The Investigator is new to the University with PHS funding
3. The University finds an investigator noncompliant with its FCOI policy or management plan

VII. Public Accessibility to FCOI information

Written Response to Requests

In the event of a public request for information on an FCOI, in compliance with PHS Policy, prior to the expenditure of any funds under a PHS funded research project, the University will make reasonable efforts to provide accessibility by written response within five business days of a request, of information concerning any significant financial interest disclosed to the University that meets PHS FCOI.

Federal References and Additional Information on Compliance

U.S. Department of Health and Human Services (Including Public Health Service including the National Institutes of Health)

- http://policy.umn.edu/Policies/Operations/Compliance/CONFLICTINTEREST_APPI.html
- [42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought](#)
- [National Institutes of Health Financial Conflict of Interest Page](#)
- [NIH Tutorial on Financial Conflict of Interest](#)