



RESEARCH FINANCIAL CONFLICTS OF INTEREST POLICY

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1. Overview

Purpose

The purpose of this **Policy** is to ensure that the personal **Financial Interests** of Drexel University employees do not compromise their objectivity in a) designing, conducting, or reporting of their **Research** activities; b) protecting the welfare of research participants; or c) developing **Intellectual Property**.

Additionally, this policy is intended to comply with the requirements of the federal regulations set forth in [42 CFR Part 50](#) and [45 CFR Part 94](#) for research funded through the **Public Health Service** (PHS). This policy shall be construed in accordance with such regulations and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

Drexel University adheres to the PHS regulations for all sponsored research, including but not limited to PHS sponsored research.

Scope

This policy applies to all Drexel University Faculty, Professional Staff Members, Students who engage in research or are otherwise a research agent of Drexel University.

2. Definitions

Compensation means any remuneration, including, without limitation, salary and payment for services not otherwise identified as salary such as consulting fees, payment of personal travel expenses, honoraria, and paid authorship. Notwithstanding the foregoing, Compensation shall not include any of the following:

1. Salary, royalties, or other remuneration paid by the University to an Investigator if the Investigator is currently employed or otherwise appointed by Drexel, including intellectual property rights assigned to Drexel and agreements to share in royalties to such rights;
2. Income from investment vehicles, such as mutual funds and retirement accounts, providing the Investigator does not directly control the investment decisions made by such vehicles;
3. Income from seminars, lectures, or teaching engagements or service on advisory committees or review panels that are sponsored by the University, 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.

CITI Conflicts of Interest Training means The Collaborative Institutional Training Initiative (CITI Program) dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.

Designated Official means an institutional official designated to solicit and review disclosures of significant financial interests from Investigators. The Designated Official is the Executive Vice Provost of Research & Innovation or such other individual as he or she may designate in writing. ORI Compliance is designated to solicit and review disclosures of Significant Financial Interests.

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Entity means any domestic or foreign, public or private, for profit or not-for-profit legal entity or organization other than the University, any agency of the Commonwealth of Pennsylvania, or the federal government.

Equity Interest means any profits of or other ownership interest in any commercial or non-profit enterprise, including common stock and other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other security convertible into an equity security.

Final Federal Financial Report or FFR means a single form consolidating the collection of financial information previously collected on the Cash Transaction Report (SF 272 and the Financial Status Report (SF269). NIH grantees now required to submit all required expenditure reports using the FFR. Further all FFR expenditure reports must be submitted to NIH electronically through the eRA Commons

Final Invention Statement and Certification or FIS means the recipient must submit a final report, whether or not the funded project results in any subject inventions, and whether or not inventions were previously reported.

Final Progress Report means a final report that is required for any grant that has ended or terminated and any award that will not be extended through award of a new competitive segment.

Financial Conflict of Interest or FCOI means a financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See [42 CFR 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research](#) for which PHS funding is sought and [NIH Grants Policy Statement: 4.1 Public Policy Requirements and Objectives 4.1.10 Financial Conflict of Interest](#).

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

Financial Interest Disclosure Process means a University maintained and operated online process for reporting SFI Disclosures.

Human Subject (PHS regulations "Protection of Human Subjects" [45 CFR Part 46](#), as administered by OHRP) means a living individual about whom an Investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Human Subjects (FDA regulations [21 CFR Part 50](#)) means an individual who is, or becomes, a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Immediate Family Member means a person's spouse/domestic partner and dependent children.

Institutional Official means person working in a research organization's business office who has signature or other authority. That person is the same as Grants.gov's Authorized Organizational Representative (AOR) and the eRA Commons' Signing Official (SO).

Institutional Review Board means an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

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Intellectual Property means creative works or ideas embodied in a form that can be shared or can enable others to recreate, emulate, or manufacture them. Intellectual property is protected by state and federal laws governing inventions, patents, trademarks, unfair competition, copyrights, trade secrets, data and Technical Data, the right of publicity, and new plant varieties. Examples of intellectual property are: inventions; patents; copyrights; designs; know-how; business, technical, and research methods; and other types of intangible business assets such as goodwill and brand recognition. An SBC's intellectual property may include what it proposes and/or generates in its participation in the SBIR/STTR programs.

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

Management Plan means a written plan instituted by the University for the management, reduction or elimination of an FCOI.

National Science Foundation or NSF means an independent federal agency created by Congress in 1950 "to promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense..." NSF is vital because we support basic research and people to create knowledge that transforms the future.

PHS-Funded Research means any Research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. Notwithstanding the foregoing, PHS-Funded Research does not include any Phase I SBIR Program application or award.

Policy means this Financial Conflict of Interest Policy.

Public Accessibility Request means prior to expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible website or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the institution that meets the following criteria:

- The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
- The Institution determines that the significant financial interest is related to the PHS-funded research; and
- The Institution determines that the significant financial interest is a financial conflict of interest.

Public Health Service or PHS 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 National Institutes of Health (NIH).

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. 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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory

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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.

Research Conflict of Interest Committee or FCOI Committee means the ad hoc Committee created by the Office of Research and Innovation, as needed, to oversee the management of FCOI.

SFI Disclosure means anything of monetary value received or held by an investigator or family member (spouse, domestic partner, parents, siblings or children), whether or not the value is readily ascertainable, that reasonably appears to be related to the investigator's institutional responsibilities.

SFI Disclosure Form means the financial disclosure form is used by "Investigators" to disclose their SFIs (i.e., domestic and foreign) to the Institution's designated official(s), for example.

Significant Financial Interest or SFI means:

(1) 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 appears to be related to the Investigator's institutional responsibilities:

(i) 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) 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

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

(2) 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; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit

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organization; 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.

Sponsor means one or more designated individual(s) responsible for providing the fellow with research training and career guidance throughout the grant award period.

Sponsored Travel means travel taken by any individual who receives and/or is paid on a PHS-funded research grant is required, by federal regulation to disclose all reimbursed or sponsored travel (i.e., that which is paid on behalf of the individual) taken on or after August 24, 2012. Travel should be disclosed to Drexel ORI within 30 days of the travel. Notwithstanding the foregoing, Sponsored Travel shall not include activities that are paid by the University, a federal, state or local government agency, an Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

Small Business Innovation Research Program or SBIR Program means a program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs. Go to [Small Business Funding Opportunities](#).

Small Business Technology Transfer or STTR means a program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs. Go to [Small Business Funding Opportunities](#).

Subrecipient means a non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants.

3. Statement of Policy and Procedure

3.1 Who needs to disclose?

- 1) Each **Investigator** who is planning to Participate in Research must disclose **Significant Financial Interest** (SFI) no later than time of proposal application or submission;
- 2) Each Investigator must submit a disclosure within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) all new SFI;
- 3) Each Investigator who is participating in funded Research must submit an updated disclosure of SFIs at least annually during the award period. The updated disclosure will include any new information that was not initially disclosed to Drexel or in any subsequent disclosure of SFI and will include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed **Equity Interest**).
- 4) Each Investigator who is submitting a proposal is required to disclose SFI no later than the time of execution.

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- 5) When research involves *Human Subjects*, the Investigator must disclose SFIs at time of initial submission, when being added as personnel, change in funding, and at the time of continuing review, if applicable.
- 6) Expenditure of funds is prohibited before the processes of disclosure, review, and management (if needed) is completed.

3.2 What is to be disclosed?

Investigators must disclose the following as related to themselves and any **Immediate Family Member**:

1. The person(s) having the interest;
2. The Investigator's relationship to such person(s);
3. The name of the *Entity* with which the Investigator has the SFI; and
4. The nature and approximate *Compensation* (monetary value) of the SFI.

3.3 What are the Disclosure Obligations in Publications or Presentations?

To promote transparency in scientific discourse, Investigators are expected to disclose their Financial Interest related to any presentation or publication of research results by the Investigator. Such interests include (i) financial interest in Entities supporting or otherwise connected to the presentation, publication or research activity, (ii) the Investigator's provision of legal consulting on the subject of the research, and (iii) any other interests that the Investigator reasonably believes could be material to members of an audience or readers assessing the opinions, advice, or work presented by the Investigator. This includes the disclosure of a financial interest in an Entity which owns or has a contractual relationship to the technology being reported or discussed.

3.4 How are SFI Disclosures Reviewed?

The *Designated Official*, through the Office of Research & Innovation, will review all disclosures indicating a potential SFI and any other relevant information (e.g., research proposal, IRB application, etc.) and determine:

1. Whether the Investigator's SFI is related to the Research; and if so,
2. Whether the SFI constitutes a *Financial Conflict of Interest* (FCOI).

If the designated official identifies an FCOI, the official will develop a *Management Plan*, including any proposed conditions or restrictions to manage the FCOI. The Executive Vice Provost for Research & Innovation will review the plan and will make a final determination as to how to manage the FCOI by accepting, rejecting or requesting input from an ad hoc *Research Conflicts of Interest Committee* (FCOI Committee).

The Executive Vice Provost for Research & Innovation is responsible for selecting members, as appropriate, for the ad hoc FCOI Committee. Ad hoc committee members will be selected based on the needs of the review and may include representation from the Institutional Official (IO), department chair, corporate compliance, Office of Research and Innovation, Office of General Council, Applied Innovation, as applicable per expertise. Actions of the FCOI Committee are reported to the Board of Trustees.

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The Designated Official may elect to conduct an expedited review instead of engaging a full committee for amendments or continuing reviews of SFIs which have been previously reviewed, appear to be related to SFIs covered under an active Management Plan or can be easily addressed by standard management plan measures.

The IRB, IACUC, or other regulatory review committee has the purview to include additional protections above and beyond the management plan to ensure risk mitigation to subjects or otherwise permit revisions to take into account a current study status or protocol design. The Investigator must comply with any management plan imposed by Drexel and upon receipt of the determination, the Investigator must either accept or submit an appeal. Funding will be held until the Investigator agrees to comply with the final management plan.

3.5 How are Management Plan Appealed?

The Investigator has ten (10) business days from receipt of the final decision to submit a written appeal to the Executive Vice Provost for Research & Innovation. The appeal should include the specific provisions being challenged, the reason for the appeal, and the justification for a different outcome. The Investigator may also provide an alternative management plan and any supplemental information that might be helpful in reviewing the appeal. After this secondary review, the decision will be final and cannot be further appealed.

3.6 How are FCOIs Managed?

When a FCOI has been determined to exist, the management plan will specify the actions that have been, and will be, taken to manage the FCOI. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- a. Public disclosure of the FCOI (e.g., when presenting or publishing the research);
- b. For Research involving human subjects, disclosure of the FCOI directly to the human subjects as approved by the *Institutional Review Board*;
- 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 or protocol;
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research (e.g., conflicted investigator may not be permitted to personally obtain informed consent from participants);
- f. Reduction or elimination of financial interest (e.g., sale of an equity interest); and
- g. Severance of relationships that create the FCOI.

The IRB, IACUC, or other regulatory review committee has the purview to include additional protections above and beyond the management plan to ensure risk mitigation to subjects or otherwise permit revisions to accounting for a current study status or protocol design.

3.7 How Will the Management Plan be Monitored?

The Office of Research & Innovation shall take such actions that it deems reasonable to audit and monitor compliance with the management plan on an ongoing basis until the completion of the Research.



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Investigators are required to comply with the management plan. If an Investigator fails to comply, the Designated Official, with the aid of the Institutional Official, and other related offices or committees (e.g., IRB, IACUC) will develop a corrective action plan. The Institution may impose sanctions for non-compliance including suspension, denial of eligibility to engage in Research, or other appropriate penalties. Such sanctions may require giving notice to professional bodies, regulatory agencies, journals, or the public.

3.8 How to Disclose New or Increased SFIs?

Any Investigator participating in an existing Research project who acquires a new or increased SFI that would otherwise be required to be disclosed under this Policy shall submit a new **SFI Disclosure** within thirty (30) days of the acquisition of the new or increased SFI through the **Financial Interest Disclosure Process**. Reporting instructions can be found at [ORI's Financial Conflicts of Interest Website](#) (*This process will transition to Novelution once the new system is implemented.)

Any University personnel joining an existing Research project who has an SFI that would otherwise be required to be disclosed under this Policy shall submit an SFI Disclosure prior to participating as an Investigator in the Research project and shall not participate as an Investigator in the Research project until an FCOI review has been completed.

In the event that a new or increased interest is disclosed to Drexel or if the University identifies a disclosed interest that was not previously reviewed in a timely manner in accordance with this policy, the **Institutional Official** will do the following, acting directly or in conjunction with a Review Committee, within sixty (60) days:

1. Determine whether an FCOI exists; and if it does,
2. Implement a management plan on an as needed basis in accordance with this policy that specifies the actions that have been, and will be, taken to manage the FCOI.

3.9 What Happens When the FCOI Is Not Identified and Managed?

1. In the event that a FCOI is not identified or managed in a timely manner, including:
 - a. Failure of an Investigator to timely disclose an SFI that is subsequently determined by the Institution to constitute an FCOI;
 - b. Drexel's failure to review or manage such an FCOI; or Investigator's failure to comply with a FCOI management plan.
 - c. Drexel will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities on the project(s) to determine whether there was any bias in the design, conduct, or reporting of the Research during the period of noncompliance.
2. The University shall fully document the following during this retrospective review:
 - a. Project number(s), e.g., IRB number(s), IACUC number(s), and title(s);
 - b. Principal Investigator (PD/PI) or contact PD/PI if multiple PD/PI model is used;
 - c. Investigator and entity resulting in the FCOI;
 - d. Reason the retrospective review was needed;
 - e. Detailed description of methodology used to conduct the Detailed methodology used for the retrospective review, including but not limited to:
 - i. Methodology of the review process.

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- ii. Composition of the review panel.
 - iii. Documentation reviewed.
- f. Findings and conclusion of the review
- 3. Should the final result find bias in the design, conduct or reporting, a final report will be drafted to include, at a minimum, the following:
 - a. The key elements documented in the retrospective review;
 - b. A description of the impact of the bias on the research project; and
 - c. DU plan of action or actions taken to eliminate or mitigate the effect of the bias.
 - d. For **PHS-Funded Research** only, DU will submit FCOI reports to the PHS awarding agency annually until the completion of the project, specifying the actions that will be taken to manage the financial conflict of interest going forward.
 - e. For PHS-Funded Clinical Research only, in any case where 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) has been designed, conducted, or reported by an Investigator with an FCOI and was not managed or reported by the Institution as policies require, DU will require the Investigator involved to disclose the FCOI in each public presentation of the results of the Clinical Research and to request an addendum to previously published presentations.
- 4. For **National Science Foundation** (NSF)-Sponsored Research only, the Institutional Official will provide notice to the NSF Office of General Counsel if the Institution finds that it is unable to satisfactorily manage FCOI.
- 5. At any time, the Institutional Official may determine that interim measures are necessary regarding the Investigator's participation in the affected PHS or NSF-Funded Research, and all other federal requirements will be followed.
- 6. Additional reporting will be completed by the Institutional Official or Designee, as required, including reporting to internal Drexel offices or external agencies.

3.10 What are the *Small Business Innovation Research Program* (SBIR)/ *Small Business Technology Transfer* (STTR) Disclosures Requirements?

Phase I and II SBIR Program or STTR applications and awards are subject to the same FCOI disclosure requirements and reviews as all other PHS-Funded Research.

3.11 What are the FCOI Training Requirements?

Investigators engaging or planning to engage in any research, at or under the auspices of Drexel, must complete **CITI Conflicts of Interest Training** prior to engaging in research and at least once every four (4) years. Investigators must also complete this training immediately in any of the following circumstances:

- a. When this policy is revised in any manner that affects the requirements applicable to PHS-Funded Investigators;
- b. When an Investigator is new to Drexel, even if the research has already begun; or
- c. When Drexel finds that an Investigator is not in compliance with this policy or an imposed management plan. A meeting with a member of the FCOI Team is also required in this instance.



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3.12 What are the Subrecipient Disclosure Requirements?

If a **Subrecipient** (e.g., subcontractors or consortium members) carries out a portion of the work, University shall take reasonable steps to ensure that any subrecipient and subrecipient Investigator complies with the applicable FCOI regulation. The University will establish, via a written agreement, including but not limited to the what's outlined below, the governing FCOI policy.

- Subrecipient will certify that its FCOI policy complies with the respective regulations and, further, subrecipient will report identified FCOIs for its investigators in a time frame that allows University to report identified FCOIs to the awarding agency.
- Alternatively, if a sub-recipient lacks a compliant FCOI policy, the subrecipient will be governed by the University's FCOI policy; University will solicit and review sub-recipient Investigator disclosures and identify, manage and report FCOIs to the **Sponsor**.

In the event that a subrecipient notifies University of an FCOI for subrecipient Investigators for which University is the prime awardee, University will promptly notify the sponsor.

3.13 What are the Record Retention Requirements?

Unless some other applicable record retention law, requirement, or policy requires a longer period of retention, records created and maintained under this Policy, including SFI Disclosures, **Sponsored Travel** and Management Plans, shall be retained by the University for a period of no less than three (3) years after the termination or completion of the Research, or as required by the applicable Federal agency. Complete the closeout process by submitting acceptable final reports consisting of **Final Federal Financial Report** (FFR), **Final Progress Report**, and the **Final Invention Statement and Certification** (FIS) to which they relate.

3.14 What are the Sanctions and Remedies for Violation of this Policy?

Whenever the Institutional Official determines that a person has violated this Policy, including any failure to make a required SFI Disclosure comply with a requirement of a Management Plan, the Institutional Official shall recommend appropriate sanctions consistent with University policies and procedures relating to faculty, employee, or other discipline. The Institutional Official is authorized to suspend, for good cause, an ongoing Research project to prevent any probable or continued violations of this Policy.

3.15 How to comply with **Public Accessibility Requests**?

Drexel University will make information available concerning identified FCOIs by Investigators (as identified in the relevant submittal to the PHS-funding unit) by a written response to any requestor within five (5) business days of a request made to foi@drexel.edu. Per PHS, rules, this information will include:

- The name of the Investigator;
- The Investigator's title and role with respect to the research project;
- The name of the entity in which the SFI is held;
- The nature of the SFI, and
- The approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public process or other reasonable measures of fair market value.



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In situations where Drexel University is working with a subrecipient, it is Drexel University's responsibility to make FCOI information publicly accessible. However, when the subrecipient Investigator is required to comply with the subrecipient's FCOI policy, the subrecipient institution will also make FCOI information publicly accessible. In these situations, Drexel University can consider including the requirement for the subrecipient institution to make FCOI information publicly available as part of the subaward agreement.

4. Responsibilities

4.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this policy, applicable tools, and monitoring. For inquiries regarding this policy, please contact the Executive Director of Research Compliance, as part of the Office for Research & Innovation (ORI).

4.2 Investigator Responsibilities

Investigators, as per the definition in this policy, are required to comply with the requirements set forth in this policy, inclusive of disclosure responsibilities, management plan implementation, and training requirements.

5. Resources

- [Drexel University Smartsheet ORI FCOI Disclosure Form](#)
- [Drexel University SBIR/STTR Procedures](#)
- Drexel University Record Management Policy
- [Drexel University Records Management Program Master Schedule](#)
- FCOI Regulation 42 CFR Part 50 Subpart F - Promoting Objectivity in Research
- Responsible Prospective Contractors [45 CFR Part 94](#)
- Protection of Human Subjects [21 CFR Part 50](#)
- Subscribe to the NIH Guide to Grants and Contracts at NIH Guide LISTSERV
- NIH Guide Notices Related to Financial Conflict of Interest
- NIH FCOI Webpage at [Financial Conflict of Interest](#)
- NIH FCOI Training Webpage at [FCOI Training](#)
- NIH FCOI FAQs at [Frequently Asked Questions \(FAQs\)](#)
- NIH Foreign Grant webpage at [Information for Foreign Grants](#)
- NIH [Important Highlights of FCOI Regulatory Requirements for Foreign Institutions](#)
- NIH ["WELCOME WAGON" LETTER - Information for New Recipient Organizations](#)
- Appendix A: PHS and Industry Regulation Chart

6. Revision and Advisory Members

6.1 Revision

Version 001/Effective Date 9/29/2025 – Research Financial Conflicts of Interest Policy

**RESEARCH FINANCIAL CONFLICTS OF
INTEREST POLICY**

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6.2 Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Advisory Members:

Advisory Members	
Marjorie Boone Assistant Director, Research Conflicts of Interest Office of Research & Innovation	Carissa Miller Research Compliance Coordinator Office of Research & Innovation
Jose Cartagena Senior Export Control & COI Specialist Office of Research & Innovation	Cassandra Myers, BS Associate Vice Provost, Research Compliance and Regulatory Affairs Office of Research & Innovation
Marisa Corbett, BA, CCRC Executive Director, Research Quality Assurance Office of Research & Innovation	John Roberts, BA, CIP Executive Director of Human Research Protections Program Office of Research and Innovation
Elizabeth Hann, BS Director of Animal Welfare, Radiation Safety, and IBC Office of Research and Innovation	Sarah Saxton, MA, MEd Assistant Vice Provost of Sponsored Programs Office of Research & Innovation
Lacee Harris, PhD Executive Director, Research Compliance Office of Research and Innovation	Jacqueline Stults, MBA, BS Research Quality Assurance/Quality Improvement Office of Research & Innovation
Shreya Laheri Research Technical Specialist Office of Research & Innovation	



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APPENDIX A

For PHS and all sponsors that follow the 2011 PHS FCOI Regulations	For NSF and all other sponsors
1. With regard to any publicly traded entity , an SFI exists if the value of any remuneration received from the entity in the twelve months <i>preceding</i> the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000 ; or with regard to any non-publicly traded entity , an SFI exists if the value of any remuneration received from the entity in the twelve months <i>preceding</i> the disclosure, when aggregated, exceeds \$5,000 , or when the Investigator (or the Investigator's Immediate Family) 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 income related to such rights and interests.	1. An equity interest that when aggregated for the Investigator and the Investigator's Immediate Family exceeded \$5,000 over the last 12 months, and/or is expected to exceed \$5,000 in value over the next 12 months as determined through reference to public prices or other reasonable measures of fair market value; or when the Investigator (or the Investigator's Immediate Family) holds a 5% or greater equity interest (e.g., partnership, ownership, stock, stock option, or other ownership interest) in a single publicly traded entity or holds any equity interest in a non-publicly traded entity; or Salary, royalties or other payments not from the University for services (e.g., consulting fees or honoraria) that when aggregated for the Investigator and the Immediate Family over the last 12 months exceeded \$5,000 or are expected to exceed \$5,000 over the next 12 months.
2. 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.	
3. Compensation made to the Investigator in which the value of compensation could be affected by the outcome of the study/research project.	
4. A proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement.	
The Term SFI does not include the following: <ul style="list-style-type: none">• Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including	

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intellectual property rights assigned to the 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.
- Travel that is reimbursed or 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.