

## Policy on Financial Conflict of Interest in Research

[DRAFT 20250821]

Policy Title	Policy on <u>Financial</u> Conflict of Interest in Research
Policy #	01.010. <del>42</del>
Policy Owner	University of Rhode Island Board of Trustees
Contact Information	Questions about this policy <del>should can</del> be directed to <u>the</u> University of Rhode Island <u>Director of Research Integrity at, Associate Vice President for Research Administration,</u> (401) 874- <del>2636</del> <u>4813</u> .
Approved By	University of Rhode Island Board of Trustees
Effective Date	
Next Review Date	No later than
Who Needs to Know About this Policy	All <del>faculty and staff</del> <u>Employees</u> of the University involved in the conduct, <u>administration, or oversight of research</u> <del>Research, or the administration or oversight of research</del> <u>Research</u> ; as well as all Investigators associated with University <u>research</u> <del>Research and development</del> regardless of professional affiliation; <del>members of the University of Rhode Island Board of Trustees</del>
Definitions	<p><b><del>Conflict of Interest</del> Management Committee.</b> <u>A committee established in accordance with the University of Rhode Island Board of Trustees Policy on Public-Private Partnership in Research and Development to advise the Designated Responsible Official on Financial Conflicts of Interest in Research.</u><del>The University of Rhode Island committee that advises the Institutional Official with respect to conflict of interest matters. The Conflict of Interest Management Committee is required by, and established in accordance with the requirements of, the University's policy on "Public-Private Partnership in Research and Development."</del></p> <p><b><u>Designated Responsible Official ("DRO").</u></b> <u>The individual responsible for reviewing disclosures of Significant Financial Interest and managing Financial Conflicts of Interest as they relate to Research. For the purposes of this policy, the Designated Responsible Official will be the Vice President for Research and Economic Development at the University of Rhode Island.</u></p> <p><del><b>DOE.</b> Department of Energy.</del></p> <p><b>Employee.</b> <u>Any person employed by the University, including but not limited to faculty, staff, or a student worker; regardless of the source of funds from which they are paid.</u><del>Any faculty member, staff member, institution</del></p>

~~official, or student who is employed by the University of Rhode Island Board of Trustees.~~

**Equity Interests.** Stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity.

**Family Member.** For the purposes of this policy, the term Family Member refers to an Investigator's spouse and any dependent children.

**Financial Conflict of Interest.** A Significant Financial Interest ~~that that the University of Rhode Island reasonably determines~~ could directly and significantly affect the design, conduct, or reporting of Rresearch.

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

~~**Institutional Official.** Individual within the University of Rhode Island that is ultimately responsible for the review of disclosures of Significant Financial Interest(s) and the management of Financial Conflicts of Interest. For purposes of this policy, the term Institutional Official shall mean the University's Vice President for Research and Economic Development.~~

**Institutional Responsibilities.** Investigator's responsibilities associated with their University of Rhode Island appointment or position, such as Rresearch; teaching; service; support; and/or administration; conference attendance, Rresearch presentations or lectures at other universities or uncompensated publication review; and certain internal and external professional committee service.

**Investigator.** Project director or principal Investigator and any other person, regardless of title or position, who is ~~independently~~ responsible for the design, conduct, or reporting of ~~research~~Research, which may include, for example, collaborators or consultants. Some sponsors have specific requirements for identifying Investigators. ~~See the Office of Sponsored Projects website for more information.~~

~~**Public Health Service (PHS) Agencies.** PHS Agencies include the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Administration for Children and Families (ACF), or Administration on Aging (AOA).~~

**Remuneration.** Remuneration includes salary and payments for services, such as consulting fees, honoraria, or paid authorship and cash or in-kind gifts from entities for the provision of services.

**Research.** A systematic investigation, including development, testing, and evaluation of ideas, designed to develop or contribute to general

knowledge. Research includes all basic, applied, clinical, translational, and demonstration activities in all academic and scholarly fields, including, but not limited to the arts, sciences, liberal arts, applied sciences, social sciences, and professions, including Research activities involving human subjects and animals.

**Significant Financial Interest.** Defined by the National Institutes of Health as a Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Family Members) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- a. With regard to any publicly traded entity, any Remuneration received from the entity in twelve (12) months preceding disclosure exceeding five thousand dollars (\$5,000) when aggregated, and any Equity Interest in the entity as of date of disclosure with a value exceeding five thousand dollars (\$5,000) when aggregated. Equity Interest value is determined through reference to public prices or other reasonable measures of fair market value.
- b. With regard to any non-publicly traded entity, any Remuneration received from entity in twelve (12) months preceding disclosure exceeding five thousand dollars (\$5,000) when aggregated; and any Equity Interest held.
- c. Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of related income.
- a-d. Travel of any value that is reimbursed or sponsored (i.e., that which is paid on behalf of the Investigator or their Family and not reimbursed to the Investigator so that the exact monetary value may not be readily available).~~A financial interest that meets any of the criteria for significance set forth below and is received or held:~~

~~b.—~~

~~By an Investigator;~~

~~By an Investigator and members of their Family; or~~

~~Solely by members of the Investigator's Family, but only if the financial interest could reasonably appear to be related to the Investigator's Institutional Responsibilities.~~

~~A financial interest is deemed to be significant if:~~

~~With regard to any publicly traded entity, any income received from the entity in twelve (12) months preceding disclosure and value of any equity interests in the entity as of date of disclosure exceeding five thousand dollars (\$5,000) when aggregated for an Investigator, Investigator's Family or business associates from a single entity (business, public or nonprofit) including 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;~~

- ~~a. With regard to any non-publicly traded entity, any Remuneration received from entity in twelve (12) months preceding disclosure, when aggregated, exceeds five thousand dollars (\$5,000); or when the Investigator holds any equity interest (e.g., stock, stock option, or other ownership interest). This does not include 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;~~
- ~~b. Intellectual property interest held by the Investigator, or Investigator's spouse or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the University of Rhode Island upon receipt of income related to such rights and interests that exceed five thousand dollars (\$5,000) in twelve (12) months preceding disclosure.~~
- ~~c. 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 Institutional Responsibilities. Excludes travel reimbursed or sponsored by federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(A), an academic teaching hospital, a medical center, or a research institute affiliated with institution of higher education.~~

**Significant Financial Interests do NOT include:**

- a. ~~s~~Salary, royalties, or other Remuneration paid by the University of Rhode Island to the Investigator if the Investigator is currently employed or otherwise appointed by the University of Rhode Island, including intellectual property rights assigned to the University of Rhode Island and agreements to share in royalties related to such rights;
- b. ~~i~~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. ~~i~~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~~Research institute that is affiliated with an institution of higher education;
- d. ~~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

	<p>hospital, a medical center, or a <del>research</del> <u>Research</u> institute that is affiliated with an institution of higher education; <u>or</u></p> <p><del>d.e. travel reimbursed or sponsored by federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(A), an academic teaching hospital, a medical center, or a</del> <u>Research institute affiliated with an institution of higher education.-</u></p>
<p><b>Statutes, Regulations, and Policies Governing or Necessitating This Policy</b></p>	<p><u>Public Health Service (PHS), 42 C.F.R. Part 50, Subpart F, 42 CFR 50: 42 CFR 50: Subpart F Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought</u></p> <p><u>Public Health Service (PHS), 45 CFR 94.4: 45 C.F.R. § 94.4, Responsibilities of Institutions Regarding Investigator Financial Conflicts of Interest</u></p> <p><u>U.S. National Science Foundation (NSF), NSF 24-1 NSF 24-1: Proposal &amp; Award Policies &amp; Procedures Guide</u></p> <p><u>U.S. Department of Energy Interim Conflict of Interest Policy Department of Energy (DOE), Interim Conflict of Interest Policy</u></p> <p><u>National Aeronautics and Space Administration (NASA), 88 F.R. 5930, Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards</u></p> <p><u>Policy on Conflict of Commitment in Research</u></p>
<p><b>Reason for Policy/Purpose</b></p>	<p>To meet the requirements of federal regulations and policies regarding <u>Financial</u> <del>e</del>Conflict of <u>I</u>nterest in <del>research</del> <u>Research</u>. To ensure that the University and its Employees participating in <del>research</del> <u>Research</u> activities conduct themselves in accordance with federal regulations and policies with regards to <u>Financial</u> <del>e</del>Conflict of <u>I</u>nterest in <del>research</del> <u>Research</u>.</p>
<p><b>Forms Related to this Policy</b></p>	<p><u>U</u><del>R</del><u>niversity Research of Rhode Island</u> Significant Financial Interest <u>and</u> <u>Outside Activity</u> Disclosure Form</p>

## Policy Statement

The University of Rhode Island (~~also, "University"~~) ~~sees great values in~~ outside activities that advance and communicate knowledge through interaction with government, industry, the community, and the public. A researcher's Financial Interest in a company or other organization (or that of their Family) may produce a real or perceived Financial Conflict of Interest if the ~~f~~Financial Interest could directly and significantly affect or appear to affect the design, conduct, or reporting of ~~research~~ Research. ~~Research that involves human subjects is subject to greater scrutiny to ensure the health and safety of human subjects.~~

~~University of Rhode Island policy, therefore, requires that~~ Investigators are required to disclose Significant ~~certain~~ fFinancial Interests. Disclosure enables the University to determine if a Significant ~~f~~Financial Interest creates a

~~Financial eConflict of iinterest or the appearance of a Financial eConflict of iinterest. The existence of a conflict, or the appearance of one, does not imply wrongdoing on anyone's part and does not necessarily mean that an Investigator may not retain their financial interest and undertake the affected research. Some conflicts must be eliminated, but the University often can work with the Investigator to manage a conflict, or the appearance of a conflict, so that the research can continue in a way that minimizes the possibility of bias in the research and preserves the objectivity of the research. Proper Effective management of a Financial eConflict of iinterest depends on full and prompt disclosure.~~

The intent of this policy is to meet ~~the~~ requirements of ~~applicable~~ federal, ~~state, and local~~ regulations and ~~federal policies~~ regarding ~~Financial eConflict of iinterest in research~~ Research. ~~(Public Health Service [PHS] regulations on Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought [42 C.F.R. Part 50, Subpart F], Responsible Prospective Contractors [45 C.F.R. Part 94], and National Science Foundation [NSF] final policy issued July 11, 1995).~~

This policy ~~shall apply~~ applies to ongoing and future activities as of the policy Effective Date ~~above~~, ~~but not to eCompleted purchases, past transactions, or past professional activities. The latter~~ are subject to applicable University policies in place at the time ~~these~~ those activities were undertaken.

The following additional policies related to conflicts of interest or commitment apply to individuals engaged in specific activities, and may prescribe corresponding pathways for self-disclosure and conflict management:

- The Policy on Conflict of Commitment in Research additionally applies to Employees engaged in sponsored research activities (and shares a common disclosure form);
- The Policy on Public-Private Partnership in Research and Development applies to Employees engaged in basic or applied Research and Development at the University;
- The Policy on Conflict of Interest and Commitment applies to all University Employees and guides compliance with the Rhode Island Code of Ethics; and
- The Policy on Consensual Relationships applies to Employees whose activity meets the definition of a consensual relationship as defined in that policy.

## I. Applicability

This policy and its attendant procedures ~~applies~~ to any University Employee identified as an Investigator responsible for the design, conduct, or reporting of research who receives and/or proposes to receive funding from external sources for Research at the University ~~activities funded or proposed for funding at the University by external sources~~. The policy also applies to an Investigator's Family Members.

Collaborators, sub-contractors, sub-recipients, and visiting scientists that are identified as Investigators must either comply with this policy and its attendant procedures or provide a certification to the Director of Sponsored Projects at the University of Rhode Island that their institutions are in compliance with pertinent federal policies and that they in turn are in compliance with their own institutional policies. ~~Subcontractors from commercial firms need make a certification only when the prime award is from a Public Health Service (PHS) Agency.~~

## II. Federal Regulations and Sponsor Policies

~~Federal regulations, specifically 42 CFR 50 and 45 CFR 94, require the University to adopt a policy governing conflicts of interest in research for all projects funded, directly or indirectly through a sub-award from another organization, by the Public Health Service of the U.S. Department of Health and Human Services other than Small Business Innovation Research and Small Business Technology Transfer programs awards.~~



~~In 1995, the National Science Foundation (NSF) added Section 510, Conflict of Interest Policies, to its grant policy manual. The National Science Foundation requires principal Investigators and all other Investigators of any NSF-funded research project to disclose their Significant Financial Interest(s) related to the research project.~~

~~These federal regulations and policies, along with State of Rhode Island ethics laws and regulations and the associated state Public-Private Partnership Act, drive the development of this policy and control its content.~~

### ~~III. State Ethics Laws~~

~~All Employees of the University of Rhode Island are subject to various provisions of Rhode Island law governing ethics and conflicts of interest in public employment. Specifically, Employees of the University must adhere to Article III, Section 7 of the Rhode Island Constitution and to the Rhode Island Code of Ethics in Government (also, Rhode Island Code of Ethics). At the University of Rhode Island, the Rhode Island Code of Ethics and other applicable state and federal laws relating to conflicts of interest are also referenced and/or incorporated into the University's policy on "Ethics and Conflict of Interest and Commitment." Members of the University community should be aware that conduct that does not violate this policy on the "Conflict of Interest in Research" may nevertheless violate the Rhode Island Code of Ethics and should seek guidance in appropriate cases. For additional information, see the University of Rhode Island policy on "Ethics and Conflict of Interest and Commitment."~~

~~This policy does not supersede or replace existing policies and practices of the University applicable to outside activities or commitments, nepotism and intellectual property. Additional information about the requirements of Rhode Island law, and University policies, may be obtained by consulting with the University General Counsel.~~

### ~~IV. Public-Private Partnership Act~~

~~The Public-Private Partnership Act recognizes that one of the primary missions of the University of Rhode Island is research and development, and that the marketing of inventions by University Employees resulting from such research will contribute to job creation and to the economic well-being of the state and the nation. The Public Private Partnership Act may allow an Employee of the University, in some cases, to have a relationship, financial or otherwise, with a company that has an interest in the research or development being performed by the Employee, even though the relationship would otherwise be prohibited by the Rhode Island Code of Ethics, when the Employee has been granted an exemption under a state approved policy adopted by University of Rhode Island Board of Trustees. Examples requiring approval and an exemption include, but are not limited to, situations in which the Employee has an ownership interest in a company that is licensing the Employee's technology from the University or situations in which the Employee has an ownership interest in a company that is sponsoring or collaborating on a research project being conducted at the University. Such relationships are allowed only with prior disclosure by the Employee, review and recommendation by the University of Rhode Island Conflict of Interest Management Committee, and approval by the Vice President for Research and Economic Development, the President, the University of Rhode Island Board of Trustees, and notice to the Rhode Island Ethics Commission. When an exemption is granted, the University is required to impose such conditions and restrictions as are necessary to manage, reduce, or eliminate any actual or potential conflict of interest. Under the terms of the Act, the presidents and vice-presidents of the University are not eligible for an exemption. For additional information, see the University of Rhode Island policy on "Public-Private Partnership in Research and Development."~~

### ~~V.II. Disclosure Process~~

~~Investigators must disclose Significant Financial Interests (1) before submitting an application for external funding, (2) at least annually thereafter, and (3) within 30 days of acquiring a new Significant Financial Interest. With the approval of the Institutional Official, and in consultation with the Conflict of Interest Management Committee, The Associate Vice President for Research Administration, in consultation with the Designated Responsible OfficialDRO and the Conflict-of-Interest Management Committee, will design procedures for the reporting of potential conflicts of Significant Financial Interests. Investigators are responsible for completing disclosures of Significant Financial Interests as described in the associated attendant procedures. These procedures will be appended to this policy and will be updated from time to time as necessary to comply with applicable law, and for other relevant reasons.~~

### **VI.III. Training**

~~All Investigators who receive and / or propose to receive funding from external sources for Research at the University must complete required training as described in the attendant procedures prior to engaging in the funded Research at the University, and at least every four (4) years thereafter. The University of Rhode Island is required to provide training to its Investigators regarding the University's policy on "Conflict of Interest in Research." Investigators funded by a PHS Agency must complete the training prior to the University charging effort to the PHS award, and at least every four (4) years thereafter. Investigators must also complete training within a period of time determined by the Designated Responsible Institutional OfficialDRO if: 1) this policy is substantively amended in a manner that affects the requirements of PHS-funded Investigators; and 2) the Designated Responsible OfficialDRO University determines that the Investigator has not complied with this policy or with a management plan related to their researchResearch.~~

### **VII.IV. Review and, Evaluation, and Resolution of Disclosures**

~~The Associate Vice President for Research Administration, in consultation with the Designated Responsible and Institutional OfficialDRO and the Conflict of InterestConflict-of-Interest Management Committee, will review financial disclosures as described in the attendant procedures. The intent of the review is to determine:~~

- ~~(1) -whether the disclosed Significant Financial Interest(s) reasonably appear to be related to the externally-funded researchResearch activity in which the Investigator is or proposes to be engaged; -~~
- ~~(2) Whether the disclosed Significant Financial Interest(s) constitute real or perceived Financial Conflict(s) of Interest; and~~
- ~~(4)(3) Whether the real or perceived Financial Conflict(s) of Interest should be managed or eliminated. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to their funded research activities. At the request of the Institutional Official, the Conflict of Interest Management Committee will review an Investigator's Significant Financial Interest to determine if that interest has the potential to directly and significantly affect the design, conduct, or reporting of the funded research; the disclosure and appropriate documentation shall be forwarded to the Conflict of Interest Management Committee for consideration.~~

~~The Conflict of Interest Management Committee will evaluate whether a Significant Financial Interest with an external entity (or travel sponsored by an external entity if travel disclosure is required) is related to a particular research project or protocol on a case-by-case basis. Examples of factors and questions that the Conflict of Interest Management Committee will consider in reviewing a disclosure include, but are not limited to:~~

- ~~• Has all the relevant information concerning the Employee's activities been acquired (i.e., has there been full disclosure)?~~



- ~~Do the Employee's relevant interests or activities suggest the potential for conflicts or the appearance of conflicts or bias?~~
- ~~Is there any indication that the Employee in their professional (University) role has improperly favored any outside entity or appears, to an uninvolved person, to have incentive to do so?~~
- ~~Has the Employee inappropriately represented the University or their relationship to the University to outside entities?~~
- ~~Does or would the Employee appear, to an uninvolved person, to be subject to incentives that might lead to conflicts or bias?~~
- ~~Is there any indication that the Employee's obligations to the University are not being met or would not be met if the activity is approved?~~
- ~~Is the Employee involved in a situation that might raise questions of bias, inappropriate use of University assets, or improper use of other resources?~~
- ~~Could the Employee's circumstances with relation to the proposed activity represent any possible violation of federal or state requirements? Of University policy?~~
- ~~Do the current engagements/proposed activities of the Employee represent potential conflicts between outside interests (e.g., working on projects simultaneously for competing business entities?)~~
- ~~Could the proposed activity withstand public scrutiny?~~

~~If the Conflict of Interest Management Committee determines that a Significant Financial Conflict of Interest (or travel sponsored by an external entity when travel disclosure is required) is reasonably related to an Investigator's Institutional Responsibilities, the Conflict of Interest Management Committee will provide a recommendation to the Institutional Official as to whether the Investigator should be required to eliminate or manage the Financial Conflict of Interest. If the Conflict of Interest Management Committee makes a recommendation of Financial Conflict of Interest management, the Conflict of Interest Management Committee will provide the Institutional Official a recommended management plan. The Institutional Official, in consultation with the Associate Vice President for Research Administration and the Investigator, will approve the management plan.~~

~~A Financial Conflict of Interest may be eliminated by divestiture of Equity Interests, termination of the relationship that gives rise to the Significant Financial Interest (such as consulting), abandoning the proposal, terminating the sponsored project, or similar measures.~~

#### **VIII.V. Management and Elimination of Financial Conflicts of Interest**

If it is determined that a real or perceived Financial Conflict of Interest may be managed, the Associate Vice President for Research Administration will develop a draft management plan and submit it for review and approval as described in the attendant procedures.

The Investigator may not commence or participate in the Research that gives rise to the Financial Conflict of Interest, or the appearance thereof, until the management plan is fully approved and executed. Once approved, the Investigator must adhere strictly to all aspects of the management plan. Compliance with the management plan will be monitored as described therein.

If it is determined that a real or perceived Financial Conflict of Interest may not be managed, the Investigator must eliminate the Significant Financial Interest before commencing or participating in the Research that gives rise to the Financial Conflict of Interest.

~~If it is determined that a Financial Conflict of Interest, or the appearance of a Financial Conflict of Interest, is present, the Investigator can eliminate the Financial Conflict of Interest by taking appropriate action (e.g., divestiture). If the~~

~~Investigator does not want to eliminate a Financial Conflict of Interest or the appearance of a Financial Conflict of Interest and Conflict of Interest Management Committee or the Conflict of Interest Management Committee together with the Institutional Official determine that a Financial Conflict of Interest can be managed, the Associate Vice President for Research Administration will develop a management plan for the Conflict of Interest Management Committee to consider.~~

~~The key elements of a management plan include the following:-~~

~~The role and principal duties of the conflicted Investigator in the research project;~~

~~Conditions of the management plan;~~

~~How the management plan is designed to safeguard objectivity in the research project;~~

~~Confirmation of the Investigator's agreement to the management plan;~~

~~How the management plan will be monitored to ensure Investigator compliance; and~~

~~Other information as needed.~~

~~Each management plan must be approved and signed by the Investigator and the Associate Vice President for Research Administration. The Investigator may not commence or participate in the research that gives rise to the Financial Conflict of Interest, or the appearance thereof, until all approvals are obtained. Management plans typically contain the requirement of an annual report completed by the Investigator and reviewed by the Conflict of Interest Management Committee or an oversight committee identified in the management plan.~~

~~The Associate Vice President for Research Administration is responsible for reporting identified Financial Conflict of Interest in cases where federal regulation or the sponsor terms and conditions require reporting. For example, for PHS-funded Investigators, a Financial Conflict of Interest must be reported to the funding agency and updated annually. Annual Financial Conflict of Interest reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last Financial Conflict of Interest report was submitted to the funding agency. The Associate Vice President for Research Administration is responsible for submitting the required information to the funding agency.~~

## **VI. Appeals**

~~If an Investigator believes that a determination made by the Conflict of Interest Management Committee regarding a Significant Financial Interest and / or a Financial Conflict of Interest is not appropriate or is based on erroneous information, they may request reconsideration by the Conflict of Interest Management Committee by submitting a written request to the chair of the Conflict of Interest Management Committee. Associate Vice President for Research Administration. If, after a second review, by the Conflict of Interest Management Committee, the Investigator still wishes to appeal the Conflict of Interest Management Committee's decision, they may appeal to the Designated Responsible Institutional Official. The Designated Responsible Institutional Official's decision is final.~~

## **VII. Reporting**

~~The Associate Vice President for Research Administration is responsible for reporting identified Financial Conflicts of Interest and any noncompliance with management plans in cases where federal regulation or the sponsor terms and conditions require reporting.~~

### **VIII. Retrospective Review**

If the University discovers a Significant Financial Interest or Financial Conflict of Interest that was not identified in the disclosure and evaluation process, the Associate Vice President for Research Administration, in consultation with the ~~Designated Responsible Official~~DRO and the Conflict-of-Interest Management Committee, will conduct a retrospective review to determine if the Significant Financial Interest is a potential Financial Conflict of Interest and if any mitigating actions are required. This review and any required mitigation report will be conducted, documented, and submitted according to federal regulation or sponsor terms and conditions.

### **IX. Sanctions for Failure to Comply**

Failure to comply with this policy or with an approved management plan will be subject to review by the ~~Designated Responsible Official~~DRO. If the ~~Designated Responsible Official~~DRO determines a policy violation has occurred, the Investigator may be subject to University discipline up to and including termination of external funding, limitation or revocation of authorization to request or receive external funding, and termination of appointment.

### **~~IX.X.~~ Public Accessibility**

This policy document will be posted on the University's public website. If it is required by federal regulation or sponsor terms and conditions, the Associate Vice President for Research Administration will make information regarding Financial Conflicts of Interest, including the management thereof, available to the public upon request. PHS Agencies require that the University make information regarding Financial Conflicts of Interest (reported to PHS Agencies) available to the public upon request. The information that must be made available includes the following, at a minimum:

- Investigator's name;
- Investigator's title and role with respect to the research;
- Name of the entity in which the Significant Financial Interest is held or from which it is received;
- Nature of the Significant Financial Interest; and
- Approximate value of the Significant Financial Interest, where the value may be expressed as being within a range as described above or, if the value of the interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement confirming that fact.

The University may also disclose information regarding the management of the Financial Conflict of Interest.

### **X. Retrospective Review**

If the University discovers a Significant Financial Interest / Financial Conflict of Interest that was not identified in the disclosure and assessment process, the Office of Research Integrity and the Conflict of Interest Management Committee will conduct a retrospective review to determine if the Significant Financial Interest is a potential Financial Conflict of Interest and if the Financial Conflict of Interest has led to the collection and/or the reporting of biased data. For PHS-funded research, this review must be completed within one hundred and twenty (120) days of the identification of the Significant Financial Interest / Financial Conflict of Interest.

If the retrospective review concludes that the research may have been biased as a consequence of the unreported Financial Conflict of Interest, the University will submit a mitigation report to the PHS Agency. The preparation of the mitigation report will be led by the Office of Research Integrity. The report will address the impact of the bias on

~~the research project and the actions the University has taken, or will take, to eliminate or mitigate the effect of the bias.~~

#### ~~XI. Sanctions for Failure to Comply~~

~~Failure to comply with this policy or with Conflict of Interest Management Committee-approved management plans will be subject to review by the Institutional Official. If the Institutional Official determines a violation has occurred, the Institutional Official may result in the filing of a complaint against the Investigator. If the conflict of interest involves a research project administered by the University, whether or not that administration is through the Office of Sponsored Projects, any action legally required by the funding agency will also be taken by the University.~~

#### ~~XII. Appeals~~

~~If an Investigator believes that a determination made by the Conflict of Interest Management Committee is not appropriate or is based on erroneous information, they may request reconsideration by the Conflict of Interest Management Committee by submitting a written request to the chair of the Conflict of Interest Management Committee. If, after a second review by the Conflict of Interest Management Committee, the Investigator still wishes to appeal the Conflict of Interest Management Committee's decision, they may appeal to the Institutional Official. The Institutional Official's decision is final.~~

#### ~~XIII.XI. Record Retention~~

The Associate Vice President for Research Administration will retain all disclosures, conflict management plans, and related documents for a period of at least three (3) years following submission of the final expenditure report for the applicable project to the sponsor of the ~~research~~Research that gives rise to the Financial Conflict of Interest(s) unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the three (3)-year period, in which case, records will be retained until completion of the action and resolution of all issues.

## Exceptions

None

## Policy Review and Revisions

(Versions earlier than the first policy number may be paper only)

Policy #	Effective Date	Reason for Change	Changes to Policy
No Policy #. Title: "Conflict of Interest in Research Policy and Procedures"	February 2019	n/a	n/a

01.010.1	November 5, 2021	Update policy to reflect Board of Trustees	Language clarification; removal of procedures
01.010.2		<u>Revised to align with the Board of Trustees Policy on Conflict of Interest and Commitment (formerly the Board of Trustees Policy on Ethics and Conflict of Interest)</u>	<u>Updated to reflect current federal agency regulations and policies at the time of revision, with some procedural content moved to Procedures.</u>