

Policy on Conflict of Interest in Research

Policy Title	Policy on Conflict of Interest in Research
Policy #	01.010.1
Policy Owner	University of Rhode Island Board of Trustees
Contact Information	Questions about this policy should be directed to University of Rhode Island Associate Vice President for Research Administration, (401) 874-2636
Approved By	University of Rhode Island Board of Trustees
Effective Date	November 5, 2021
Next Review Date	No later than December 31, 2026
Who Needs to Know About this Policy	All faculty and staff of the University involved in the conduct of research, or the administration or oversight of research as well as all Investigators associated with University research and development regardless of professional affiliation; members of the University of Rhode Island Board of Trustees
Definitions	<p>Conflict of Interest Management Committee. 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."</p> <p>Employee. Any faculty member, staff member, institution official, or student who is employed by the University of Rhode Island Board of Trustees.</p> <p>Equity Interests. Stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity.</p> <p>Family Member. For the purposes of this policy, the term Family Member refers to an Investigator's spouse and any dependent children.</p> <p>Financial Conflict of Interest. A Significant Financial Interest that the University of Rhode Island reasonably determines could directly and significantly affect the design, conduct, or reporting of research.</p> <p>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.</p> <p>Institutional Responsibilities. Investigator's responsibilities associated with their University of Rhode Island appointment or position, such as research; teaching; administration; conference attendance, research presentations or lectures at other universities or uncompensated</p>

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, 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.

Significant Financial Interest. A financial interest that meets any of the criteria for significance set forth below and is received or held:

1. By an Investigator;
2. By an Investigator and members of their Family; or
3. 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:

- a. 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, honoraria¹, paid authorship). Equity Interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- b. With regard to any non-publicly traded entity, 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;

	<p>c. 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.</p> <p>d. 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.</p> <p>Significant Financial Interests do NOT include:</p> <p>a. 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;</p> <p>b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;</p> <p>c. 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;</p> <p>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 hospital, a medical center, or a research institute that is affiliated with an institution of higher education.</p>
<p>Statutes, Regulations, and Policies Governing or Necessitating This Policy</p>	<p>42 CFR 50: Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought</p> <p>45 CFR 94.4: Responsibilities of institutions regarding Investigator financial conflicts of interest</p>
<p>Reason for Policy/Purpose</p>	<p>To meet the requirements of federal regulations and policy regarding conflict of interest in research. To ensure that the University and its Employees participating in research activities conduct themselves in accordance with federal regulations and policy with regards to conflict of interest in research.</p>
<p>Forms Related to this Policy</p>	<p>University of Rhode Island Significant Financial Interest Disclosure Form</p>

Policy Statement

The University of Rhode Island (also, University) sees great value 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 financial interest could directly and significantly affect or appear to affect the design, conduct, or reporting of 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 disclose certain financial interests. Disclosure enables the University to determine if a financial interest creates a conflict of interest or the appearance of a conflict of interest. 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 management of a conflict of interest depends on full and prompt disclosure.

The intent of this policy is to meet requirements of federal regulation and federal policy regarding conflict of interest in 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 to ongoing and future activities as of the Effective Date above, but not to completed purchases, past transactions, or past professional activities. The latter are subject to applicable University policies in place at the time these activities were undertaken.

Applicability

This policy applies to any University Employee responsible for the design, conduct, or reporting of research activities funded or proposed for funding at the University by external sources. The policy also applies to an Investigator's Family.

Collaborators, sub-contractors, sub-recipients, and visiting scientists that are identified as Investigators must either comply with this policy 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.

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.

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." 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."

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.

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."

Disclosure Process

With the approval of the Institutional Official, and in consultation with the Conflict of Interest Management Committee, the Associate Vice President for Research Administration will design procedures for the reporting of

potential conflicts of interest. Investigators are responsible for completing disclosures of Significant Financial Interests as described in the associated procedures. Those 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.

Training

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 Institutional Official if, 1) this policy is substantively amended in a manner that affects the requirements of PHS-funded Investigators; or 2) the University determines that the Investigator has not complied with this policy or with a management plan related to their research.

Review, Evaluation, and Resolution of Disclosures

The Associate Vice President for Research Administration and Institutional Official will review financial disclosures to determine whether the disclosed Significant Financial Interest(s) reasonably appear to be related to the funded research activity in which the Investigator is engaged. 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.

Management of Financial Conflicts 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:

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

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.

Public Accessibility

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.

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.

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.

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.

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 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