

THE  
UNIVERSITY  
OF RHODE ISLAND  
DIVISION OF RESEARCH  
AND ECONOMIC  
DEVELOPMENT

**Conflict of Interest in Research  
Policy and Procedures**

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## 1.0 POLICY STATEMENT

The University of Rhode Island (URI) 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 his or her immediate 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.

URI policy, therefore, requires that investigators disclose certain financial interests. Disclosure enables URI 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 his or her financial interest and undertake the affected research. Some conflicts must be eliminated, but often URI 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 depends on full and prompt disclosure.

This policy shall apply to ongoing and future activities, 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.

## 2.0 APPLICABILITY

This policy applies to any URI 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 the 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 URI Director of Sponsored Projects 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 the Public Health Service (PHS).

## 3.0 DEFINITIONS

**Conflict of Interest Management Committee (CIMC)** means URI's committee that advises the Institutional Official with respect to conflict of interest matters. A CIMC is required as part of the Public/Private Partnership Act of 2003.

**Designated Official** means the URI staff member responsible for supporting the Institutional Official in implementing this Policy. The Designated Official is the Director of Research Compliance.

**Employee** means any paid member of the University community, faculty, appointed personnel, classified staff, and student employees, whether full-time, part-time or contract employees.

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

**Family** means an Investigator's parents, spouse, children and their spouses, siblings, and their spouses and their children.

**Financial Conflict of Interest** means a Significant Financial Interest and for PHS Investigators, reimbursed or sponsored travel that URI reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

**Institutional Official** means the individual within URI that is ultimately responsible for the review of disclosures of Significant Financial Interests and the management of Financial Conflicts of Interest. The Institutional Official is the Vice President for Research and Economic Development.

**Institutional Responsibilities** means the Investigator's responsibilities associated with his or her URI appointment or position, such as research; teaching; administration; conference attendance, research presentations or lectures at other universities or uncompensated publication review; and certain internal and external professional committee service.

**Investigator** means the 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.

**Outside Professional Activities** means compensated and uncompensated activities undertaken outside of an Investigator's Institutional Responsibilities.

**Public Health Service (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).

**Related Entity** means any for profit or non-profit entity in which the Investigator, alone or in combination with his or her Family, holds a Significant Financial Interest.

**Remuneration** includes salary and payments for services, such as consulting fees, honoraria or paid authorship, and cash or in kind gifts from entities for which you provide services.

**Significant Financial Interest** means 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 his or her 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 12 months preceding disclosure and value of any equity interests in the entity as of date of disclosure exceeding \$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;
- b. With regard to any **non-publicly traded entity**, any remuneration received from entity in 12 months preceding disclosure, when aggregated, exceeds \$5,000; or when 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;
- 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 URI upon receipt of income related to such rights and interests that exceed \$5,000 in 12 months preceding disclosure.
- d. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of Investigator and not reimbursed to 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 Interest does NOT include:

- a. Remuneration from URI (salary, royalties, honoraria, expense reimbursement or any other remuneration);
- b. Remuneration paid to an Investigator's Family by any entity that would not reasonably appear to be related to the Investigator's Institutional Responsibilities;
- c. Remuneration from authorship of academic or scholarly works, regardless of the source;
- d. Remuneration from seminars, lectures, or teaching engagements sponsored by, or from advisory committees or review panels for, U.S. Federal, state, or local governmental agencies; U.S. institutes of higher education as defined at 20 U.S.C. 1001(a); U.S. research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers; and
- e. Investment by a mutual fund, pension fund or other investment fund over which the investigator or his/her immediate family member does not exercise management of fund investment.

## 4.0 FEDERAL AND STATE LAWS AND REGULATIONS

Federal regulations, specially 42 CFR 50 and 45 CFR 94, require the university to adopt a policy governing conflicts of interest in research. These federal regulations apply to all projects funded, directly or

indirectly through a sub-award from another organization, by the PHS of the U.S. Department of Health and Human Services other than SBIR and STTR awards.

Faculty members are also subject to various provisions of Rhode Island law governing ethics and conflicts of interest in public employment. All employees of the public institutions of higher education in Rhode Island must adhere to Article III, Section 7 of the R.I. Constitution, the R.I. Code of Ethics, and the Public/Private Partnership Act (R.I.G.L. §16-59-26). The purpose of the Public/Private Partnership Act is to allow the URI, Rhode Island College, and the Community College of Rhode Island to enter into public/private partnerships in education that involve faculty and staff members from those institutions and encourage the marketing of inventions developed by faculty and staff for the benefit of both the inventor and the public, while continuing to ensure that Rhode Island's public employees adhere to the highest standards of ethical conduct.

This policy does not supersede or replace existing policies and practices of the University applicable to outside activities or commitments, nepotism and intellectual property.<sup>1</sup> Additional information about the requirements of Rhode Island law may be obtained by consulting the University General Counsel.

## **5.0 PROCEDURE**

The Institutional Official will be responsible for administering the Conflict of Interest in Research Policy. The Institutional Official may designate Designated Official to perform his/her responsibilities under the policy. The Institutional Official will be responsible for providing reports to outside funding agencies as may be required by federal regulations or the terms of sponsored research agreements.

With the approval of the Institutional Official, and in consultation with the Conflicts of Interest Management Committee (CIMC), the Designated Official will design procedures for the reporting of potential conflicts of interest. The Designated Official will also administer the CIMC, assist faculty and other university employees in identifying, managing or eliminating conflicts of interest and will periodically inform the university community about the policy and other issues relating to conflicts of interest.

The general counsel is designated as the University's conflict of interest legal advisor who will assist the Institutional Official, CIMC, and the Designated Official with respect to the requirements of state and federal law and university rules.

### **5.1 Disclosure Requirements**

Full and prompt disclosure of Significant Financial Interests and for PHS Investigators, reimbursed or sponsored travel as described in the Section 5.1.2, is critical to URI's ability to identify, manage, and eliminate Financial Conflicts of Interest.

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<sup>1</sup> In particular all state and public employees, including university employees, are governed by the provisions of the State Code of Ethics found Chapter 14, Title 36 of the General Laws of Rhode Island and Regulations promulgated by the Rhode Island Ethics Commission. Members of the university community should be aware that conduct that does not violate this policy may nevertheless violate the Code of Ethics and should seek guidance in appropriate cases.

### 5.1.1 Non-PHS Funded Investigators

There are two types of disclosures, described below, which must be made

1. **Proposal-related Disclosures.** Prior to submitting proposals for internal or external funding, the Investigators identified in the proposal and, if requested by the Institutional Official or the Designated Official, other Investigators associated with the proposal must disclose his or her Significant Financial Interests. If the Investigator has a Significant Financial Interest, the individual must provide additional information regarding the relationship of the project to the Significant Financial Interest. The full disclosure must be filed prior to routing the proposal for Department, Lab or Center Head approval. Additionally, if the funding is awarded, the proposal disclosure will be verified to ensure the information is still accurate.
2. **Ad hoc Disclosures.**
  - a. When an Investigator joins a research project already in progress, an Investigator must disclose to the Designated Official on an ad hoc basis his or her Significant Financial Interests prior to the Investigator commencing participation in the research project.
  - b. An Investigator must disclose to the Designated Official on an ad hoc basis any new Significant Financial Interest within 30 days following the date on which the Significant Financial Interest is acquired or arises.

### 5.1.2 PHS Funded Investigators

There are four types of disclosures, described below, which must be made

1. **Proposal-related Disclosures.** Prior to submitting proposals for internal or external funding, the Investigators identified in the proposal and, if requested by the Institutional Official or the Designated Official, other Investigators associated with the proposal, must disclose his or her Significant Financial Interests. If the Investigator has a Significant Financial Interest, the individual must provide additional information regarding the relationship of the project to the Significant Financial Interest. The full disclosure must be filed prior to routing the proposal for Department, Lab or Center Head approval. Additionally, if the funding is awarded, the proposal disclosure will be verified to ensure the information is still accurate.
2. **Ad hoc Disclosures**
  - a. When an Investigator joins a research project already in progress, an Investigator must disclose to the Designated Official on an ad hoc basis his or her Significant Financial Interests prior to the Investigator commencing participation in the research project.
  - b. An Investigator must disclose to the Designated Official on an ad hoc basis any new Significant Financial Interest within 30 days following the date on which the Significant Financial Interest is acquired or arises.
3. **Travel Disclosures.** Investigators must disclose the occurrence of any reimbursed or sponsored travel undertaken by the Investigator related to his or her Institutional Responsibilities, and URI must determine if the travel has the potential to bias funded research.

Travel disclosures must be made if travel is reimbursed or sponsored by an organization other than:

- URI
- U.S. federal, state or local governmental agencies
- U.S. institutes of higher education

- U.S. research institutes affiliated with institutes of higher education; and
- U.S. academic teaching hospitals and medical centers.

Travel disclosures must be made within 30 days following reimbursement or within 30 days following the completion of the trip if the organization or entity funds the travel directly. The travel disclosure must include at a minimum, the purpose of the trip, the identity of the organization or entity funding the travel, the destination, the duration of the trip (usually days), and the relationship between the trip and the PHS Investigator's proposals and awards.

Investigators may "estimate" their travel and report it in advance of the trip either on a case-by-case basis or during the annual disclosure process. The Designated Official will decide if additional information is needed to determine whether the travel constitutes a Financial Conflict of Interest.

4. **Annual Disclosures.** Investigators must disclose their Significant Financial Interests to the Designated Official on an annual basis through the submission of a Significant Financial Interest Disclosure Form as part of the Noncompeting Continuation Process or other Process.

## 5.2 Training

URI is required to provide training to its Investigators regarding the Conflict of Interest in Research Policy & Procedures. PHS funded investigators must complete the training prior to URI charging effort to the PHS award, and at least every four years thereafter. Investigators must also complete training within a period of time determined by the Institutional Official if (i) this Policy is substantively amended in a manner that affects the requirements of PHS funded Investigators; or (ii) URI determines that the Investigator has not complied with this Policy or with a management plan related to his or her research.

Financial Conflict of Interest training is available on the CITI Program at [www.citiprogram.org](http://www.citiprogram.org).

## 5.3 Review, Evaluation, and Resolution of Disclosures

The Designated Official will review financial disclosures containing significant financial interests. If the Designated Official determines that a disclosed financial interest or activity presents a potential conflict of interest related to a particular research project, s/he will forward said potential conflict to CIMC or a subcommittee of CIMC for review. The CIMC (or subcommittee) will determine whether a 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 using the following general considerations:

- Is the financial interest with a sponsor, subcontractor, supplier or lessor of goods, materials, proprietary information, services, or facilities of the investigator's current or proposed research?
- Will the entity likely make use of the research or scholarly work - either directly or indirectly?
- Is the financial interest with a member of an industry, trade, or advocacy group that funds the involved research or scholarly work?
- Is the entity manufacturing, commercializing or developing a product that is being used, evaluated, or further developed by the research or scholarly work at issue?
- Will the entity receive materials, data, or other information from the investigator?
- Is the entity a competitor of the investigator's sponsor?

- Does the entity have some other relationship not described above that could be related to or could be affected by the investigator's university responsibilities?

If the CIMC (or subcommittee) determines that a financial interest (or travel sponsored by an external entity when travel disclosure is required) is reasonably related to an investigator's institutional responsibilities, CIMC (or subcommittee) will determine whether the Investigator will be required to eliminate or manage the Financial Conflict of Interest, as appropriate.

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; and similar measures.

### *5.3.1 Management of Financial Conflicts of Interest*

If the Investigator does not want to eliminate a Financial Conflict of Interest or the appearance of a Financial Conflict of Interest and CIMC determines that it can be managed, the Investigator must develop a written management plan. The Designated Official will assist the Investigator in developing the plan.

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.

The management plan must confirm that five activities that are prohibited under the Public/Private Partnership Act will not occur. The prohibited activities include:

1. Outside activities and/or relationships in which the faculty or staff member diverts to external businesses or entities or other institutions, opportunities for research support that could have been obtained by the institution.
2. Participation in institutional research which is funded by a grant or contract from a business or entity in which the employee or a member of his or her family or his or her business associate, separately or in the aggregate, has a controlling ownership interest.
3. Assignment of students to research projects sponsored by a business or entity in which the employee or a member of his or her family or his or her business associate, separately or in the aggregate, has a substantial ownership interest.
4. Outside activities in which an institution's student or employee is directly or indirectly supervised by the individual seeking the exemption or if the individual in any way supervises or evaluates the student or employee as part of his or her institutional duties.
5. Direct supervision of any student or employee in one's capacity as a university employee and in one's capacity as an official, employee or agent of the private company, business or entity.

Approved management plans must include an oversight committee that includes a group of non-conflicted scientists and staff members. Additionally, the Designated Official or designee shall serve on

the committee as an *ex officio* member. The charge of the oversight committee and the frequency of meetings are dependent on each management plan. However, all oversight committees are required to report to CIMC no less than annually on the results of their review.

Each management plan must be approved by CIMC, approved and signed by the Investigator, his or her Department Head, the Institutional Official, the President of the University, and ultimately, the Rhode Island Board of Education. To gain approval from the Rhode Island Board of Education, the Investigator must complete a Request for Exemption of the Rhode Island Public/Private Partnership Act. A final review is also completed by the Rhode Island Ethics Commission. The Designated Official will assist the Investigator in preparing the appropriate Request for Exemption documents.

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 an oversight committee identified in the management plan.

For PHS-funded investigators, financial conflicts of interests must be reported to the funding agency and updated annually. Annual FCOI 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 FCOI report was submitted to the funding agency. The Designated Official will assist the Investigator in submitting the required information to the funding agency.

Disclosures and documentation of plans to eliminate, minimize, or manage possible conflicts of interest will be maintained by the Designated Official in accordance with Section 10.0.

## **6.0 PUBLIC ACCESSIBILITY**

PHS requires URI make information regarding Financial Conflict of Interests reported to PHS 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, which 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.

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

## **7.0 RETROSPECTIVE REVIEW**

If URI discovers a SFI/FCOI that was not identified in the disclosure and assessment process, the Office of Research Integrity and CIMC will conduct a retrospective review to determine if the SFI is a potential FCOI and if the FCOI has led to the collection and/or the reporting of biased data. For PHS funded research, this review must be completed within 120 days of the identification of the SFI/FCOI.

If the retrospective review concludes that the research may have been biased as a consequence of the unreported FCOI, URI will submit a mitigation report to the PHS. The preparation of the mitigation report will be lead by the Office of Research Integrity. The report will address the impact of the bias on the research project and the actions URI has taken, or will take, to eliminate or mitigate the effect of the bias.

## **8.0 SANCTIONS FOR FAILURE TO COMPLY**

Failure to comply with this policy or with CIMC 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 faculty member. 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.

## **9.0 APPEALS**

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

## **10.0 RECORD RETENTION**

The Designated Official will retain all disclosures, conflict management plans, and related documents for a period of at least three 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, unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the three-year period, in which case, records will be retained until completion of the action and resolution of all issues.

## **11.0 RESOURCES**

Federal Financial Conflict of Interest - <http://grants.nih.gov/grants/policy/coi/>

## 12.0 CONTACTS

| Subject                             | Office                        | Telephone | Website   |
|-------------------------------------|-------------------------------|-----------|---|
| Conflict of Interest                | Office of Research Compliance | 874-2636  | <a href="http://www.uri.edu/research/tro/about/conflict/index.html">http://www.uri.edu/research/tro/about/conflict/index.html</a>         |
| Research Compliance                 | Office of Research Compliance | 874-2636  | <a href="http://www.uri.edu/research/tro/offices/compliance/index.html">http://www.uri.edu/research/tro/offices/compliance/index.html</a> |
| Requirements under Rhode Island law | Office of General Counsel     | 874-4486  |   |
| Sponsored Research                  | Office of Sponsored Projects  | 874-2775  | <a href="http://www.uri.edu/research/tro/offices/sponproj/index.html">http://www.uri.edu/research/tro/offices/sponproj/index.html</a>     |