THE
UNIVERSITY
OF RHODE ISLAND

PROCEDURES for the Policies on Financial Conflict of Interest in Research and Conflict of Commitment in Research

Policy #: 01.010.3 & 01.018.2

Purpose

These procedures support the University's *Policy on Financial Conflict of Interest in Research and the Policy on Conflict of Commitment in Research* ("the Policies").

Definitions

Definitions of all terms used in this document can be found in the relevant Polices.

Introduction

The University's policies on Financial Conflict of Interest in Research and Conflict of Commitment in Research require URI Employees responsible for the design, conduct, or reporting of Research (i.e., Investigators) funded or proposed for funding at the University by external sources to disclose Significant Financial Interests (SFIs) and Outside Activities and abide by any decisions made by the Designated Responsible Official regarding the elimination or management of Financial Conflicts of Interest and Conflicts of Commitment in Research.

This document, as amended from time to time, has been established to ensure compliance with the above policies.

Questions regarding these procedures should be directed to the Director of Research Integrity at researchintegrity@etal.uri.edu or (401) 874-4813.

Disclosing Significant Financial Interests and Outside Activities

Investigators[1] must complete disclosures on the URI Research Significant Financial Interest and Outside Activity Disclosure Form which can be accessed through the Conflict of Interest Module in InfoEd. To access the form:

1) Log into InfoEd (URI ID and password are required to log in).
2) Click on the "Conflict of Interest and Commitment" tab in the left toolbar.
3) Click on "Create/Update Disclosure."
    a. If a disclosure form has been previously completed, select "Edit/Submit Disclosure" to edit and submit the form.
    b. If a disclosure form has not been previously completed, select "Create Initial Disclosure" to create an initial disclosure.

[1] External collaborators at institutions lacking a compliant FCOI / Conflict of Commitment policy may use a different disclosure form. Contact the Office of Research Integrity for more information.

Full and prompt disclosure of SFIs and Outside Activities is critical to URI's ability to identify, manage, and eliminate Financial Conflicts of Interest and Conflicts of Commitment.

1. **Proposal-Related Disclosures**. Prior to submitting proposals for external funding, the Investigators identified in the proposal and, if requested by the Designated Responsible Official, other Investigators associated with the proposal must disclose their SFIs and Outside Activities. When an Investigator reports an SFI, the individual must provide additional information regarding the relationship of the proposed project to the SFI. The full disclosure must be filed prior to routing the proposal for Department, Lab, or Center Head approval. Additionally, if 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 an externally funded research project already in progress, an Investigator must disclose on an ad hoc basis his or her SFIs and Outside Activities prior to the Investigator commencing participation in the research project.
    b. An Investigator must disclose on an ad hoc basis any new SFIs or Outside Activities within 15 days following the date on which the SFIs or Outside Activities are acquired or arise.
3. **Annual Disclosures.** Investigators must disclose their SFIs and Outside Activities on an annual basis throughout the term of the external funding.

Examples of Significant Financial Interests and Outside Activities

- An Investigator receives payment for consulting activities from a company that may be impacted by the Investigator's research study.
- An Investigator holds equity interest in a business that may be impacted by the Investigator's research study.
- A faculty member's consulting activities consume so much time that it compromises their research and teaching responsibilities and work product.
- A faculty member serves as PI on a grant and wants to subcontract work to their (or their family member's) personal consulting business, which would result in personal financial gain.

Training

Required training is completed via the Collaborative Institutional Training Initiative (CITI) program. Instructions for accessing the CITI program can be found on the URI CITI Guidance website. The required course is titled "Conflicts of Interest." Training must be completed before proposal submission and repeated every two (2) years.

Review and Evaluation of Disclosures

The Associate Vice President for Research Administration, in consultation with the Designated Responsible Official and the Conflict-of-Interest Management Committee as needed, will evaluate disclosed SFIs and Outside Activities on a case-by-case basis to determine if they constitute real or perceived Financial Conflicts of Interest or Conflicts of Commitment.

Examples of factors and questions that will be considered in reviewing a disclosure include, but are not limited to:

- Has all the relevant information concerning the Investigators' SFIs and Outside Activities been acquired (i.e., has there been full disclosure)?
- Do the Investigators' SFIs or Outside Activities suggest the potential for conflicts or the appearance of conflicts or bias?
- Is there any indication that the Investigator 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 Investigator inappropriately represented the University or their relationship to the University to outside entities?
- Does or would the Investigator appear, to an uninvolved person, to be subject to incentives that might lead to conflicts or bias?
- Is there any indication that the Investigator's obligations to the University are not being met or would not be met if the activity were approved?
- Is the Investigator involved in a situation that might raise questions of bias, inappropriate use of University assets, or improper use of other resources?
- Could the Investigators' 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 Investigator represent potential conflicts between outside activities (e.g., working on projects simultaneously for competing business entities?)
- Could the proposed activity withstand public scrutiny?
- What is the source of the external funding?

Elimination and Management of Conflicts

If it is determined that a real or perceived Financial Conflict of Interest or Conflict of Commitment exists, the Associate Vice President for Research Administration, in consultation with the Designated Responsible Official and the Conflict-of-Interest Management Committee as needed, will propose a plan to eliminate or manage the conflict.

- A Financial Conflict of Interest or Conflict of Commitment may be **eliminated** by divestiture of Equity Interests, termination of the relationship that gives rise to the Significant Financial Interest or Outside Activity (such as consulting), abandonment of the proposal, termination of the sponsored project, or similar measures.
- A Financial Conflict of Interest or Conflict of Commitment may be **managed** by appointment of an alternative Investigator for the project, implementation of external monitoring of the project, restriction of Investigator decision-making, modification of the research plan, disclosure of the conflict to project personnel and participants, strict allocation or management of time, or similar measures.

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 of Conflict of Commitment, 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 authority identified in the management plan.