

Rhode Island College Financial Disclosure Policy for Investigators Conducting Research or Other Activities Supported by External Grant Funds

The federal government requires that the college establish and administer a financial disclosure and conflict of interest policy for externally-funded investigators, as well as a program for training investigators in that policy. This requirement is designed to ensure appropriate management of actual or potential conflicts of interest. The Rhode Island College policy fulfills the requirements of grantee institutions as put forth in the National Institutes of Health's guidelines (see http://grants.nih.gov/grants/policy/coi/) and the National Science Foundation's conflict of interest policies (see http://grants.nih.gov/grants/policy/coi/) and the College's faculty and staff, so that public trust and confidence in the college's sponsored activities are insured.

Additionally, the Rhode Island Board of Governors of Higher Education's policy on conflict of interest dictates that no person employed in any capacity under the Board's jurisdiction shall have any interest, financial or otherwise, direct or indirect, or engage in any business, employment transaction, or professional activity, or incur any obligation of any nature, which is in substantial conflict with the proper discharge of his/her duties or employment in the public interest. The college is responsible for managing, reducing, or eliminating any actual or potential conflict of interest that may be presented by the financial interest of an investigator. College personnel are also subject to the Code of Ethics set forth in Rhode Island General Laws 36-14-1 et seq. In those instances where the Code of Ethics is more stringent than the policy set forth here, the Code of Ethics shall prevail.

Therefore, the college requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interest in relation to a sponsored project. This obligation pertains to any individual who meets the definition of investigator on an externally support project involving research, education, or community service.

I. Definitions.

a. Conflict of Interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the college, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, not the character or actions of the individual. For purposes of this policy, a conflict of interest exists when the college, through procedures described here, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of a sponsored project.

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- b. Investigator is the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of externally funded research or proposing such funding. Regulations can apply to collaborators, consultants, post-doctoral fellows, graduate students, and others. Regulations apply to any individual meeting the definition of "investigator" at both awardee and sub-recipient organizations,
- c. **Research Integrity Officer (RIO)** is designated by the college to ensure institutional compliance with this policy. The RIO is the individual to whom Significant Financial Interests (SFI) are disclosed, and is assigned the Financial Conflict of Interest (FCOI) role for reporting purposes in the NIH's eRA (Electronic Research Administration) Commons website. The RIO is the Director of the Office of Research and Grants Administration (ORGA).
- d. Conflict of Interest Review Committee (CIRC) reviews investigator financial disclosure information to determine if a significant financial interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The CIRC determines any conditions or restrictions that should be imposed to mitigate the FCOI. The CIRC consists of the RIO, the college's legal counsel, and a faculty member appointed by the Vice President for Academic Affairs.
- e. **Significant Financial Interest (SFI)** means one or more of the following interests, if it reasonably appears to be related to any of the Investigator's institutional responsibilities, including all research, teaching and/or service to the college:
 - i. *Publicly traded entity:* a SFI exists if the value of any remuneration received from a publicly traded entity in the twelve months preceding the disclosure *and* the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. Remuneration includes any salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - ii. *Non-publicly traded entity*: a SFI exists if the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, *or* when the Investigator (or spouse, partner, or dependent children) owns *any* equity interest, regardless of dollar value.
 - iii. Intellectual property rights and interests (e.g. patents and copyrights) upon receipt of income related to such rights and interests. This does not include any income received from Rhode Island College for intellectual property rights assigned to the college based on agreements to share in the royalties related to such rights in conformity with the college's Intellectual Property policy, http://www.ric.edu/administration/pdf/IntellectualPropertyPolicyAugust2011.pdf.
 - iv. *Reimbursed or sponsored travel* related to institutional responsibilities, including instruction, research, or service to Rhode Island College. **Excluded** is any travel

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reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research center affiliated with an institution of higher education. *Travel that is reimbursed by Rhode Island College from a sponsored fund account whose sponsor is an entity that is not one of those exempt entities shall be treated as a SFI.* Specific details to be disclosed are: name of entity sponsoring the travel, purpose, destination and duration of the travel. Additional information, including the estimated cost of travel, may be requested by the RIO and must be furnished upon request.

f. Exclusions. The term Significant Financial Interest does not include: a) salary, royalties or other remuneration from Rhode Island College; b) income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; c) income from seminars, lectures or teaching engagement sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with institutions of higher education; d) income from service on advisory committees or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with institutions of higher education.

II. Timing of Required Disclosures.

- a. Investigators must provide all required financial disclosures at the time that institutional approval is sought for the associated grant proposal through the Proposal Summary and Approval Form (PSAF) for submitting a proposal.
 - i. Once chair and dean signatures have been obtained on the PSAF, supporting documentation identifying the business enterprise or entity involved and the nature and amount of the interest should be attached and submitted to the RIO in a sealed envelope marked "Confidential."
- b. Investigators also must update those financial disclosures:
 - i. Within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage or inheritance) any new SFI; and
 - ii. Annually within the period of the award, beginning with the anniversary date of the original disclosure.
- III. **Review of Financial Disclosures.** The following process shall apply to financial disclosures submitted by investigators.
 - a. **Determination of Financial Conflicts of Interest**. The RIO shall review each disclosed SFI; determine whether such SFI relates to externally funded activities, and, if so related, make a preliminary determination as to whether a Financial Conflict of Interest (as defined below) exists. A Financial Conflict of Interest exists when the review reasonably determines that a significant financial interest could directly and significantly

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affect the design, conduct or reporting of the proposed sponsored project. If initial determination concludes that there may be a potential for Financial Conflict of Interest, disclosure information will be referred to the CIRC. The CIRC shall make a final determination on the status of the Financial Conflict of Interest and what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential Financial Conflicts of Interest arising from the disclosed SFI.

- b. **Financial Conflicts of Interest exist** when the CIRC reviews the research, the financial interests in question, and the areas of conflict, and determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of externally funded activities.
- c. Management Plan for Financial Conflicts of Interest. If the CIRC determines that a SFI constitutes a Financial Conflict of Interest, the committee devises a plan for management of the Financial Conflict of Interest with a combination of elements it deems most conducive to the continued objective pursuit of research. The Management Plan may include conditions or restrictions to manage, reduce, or eliminate Financial Conflicts of Interest. These may include, but are not limited to: 1) monitoring of research by independent reviewers; 2) modification of the research plan; 3) disqualification from participation in the portion of the federally funded activity that would be affected by SFI; 4) divestiture of SFI; 5) severance of relationships that create conflicts; or 6) public disclosure of Financial Conflicts of Interest. Investigators affected by the Management Plan shall be given opportunity to review and comment on the conditions or restrictions. Investigators who are dissatisfied with the Management Plan may appeal to the President or her/his designee, who will consult with the investigator(s) and CIRC as s/he deems necessary and appropriate to the particular circumstance. The decision of the President or her/his designee shall be final.
- d. **Memorandum of Understanding.** The approved Management Plan shall be incorporated into a Memorandum of Understanding between Rhode Island College and the investigator(s) that details the conditions or restrictions imposed, if any, upon the investigator(s) in the conduct of the project or in the relationship with the business enterprise or entity. The Memorandum of Understanding shall be signed by the President or her/his designee and the investigator(s).
- e. **Records** of investigator financial disclosures and actions taken to manage actual or potential conflicts of interest shall be retained by ORGA until three years after the termination of the award to which they are related or the resolution of any government action involving those records. ORGA shall maintain records pertaining to each disclosure in strict confidence. Access to such records will be limited to the faculty member, the CIRC, the President or her/his designee, and others with a legal right to review the records.
- f. **Violations of this policy**, such as willful concealment of Financial Interests, may result in sanctions being imposed upon the investigator. The CIRC will review allegations of violations and make recommendations to the President or her/his designee regarding



the imposition of sanctions. The President's or her/his designee's decision with regard to imposition of sanctions is final. If the violation results in a concurrent proceeding under college policies regarding misconduct-in-science

(<u>http://www.ric.edu/orga/policies_misconduct.php</u>), the CIRC shall defer decision on sanctions until the misconduct-in-science process is completed. In addition, the college shall follow federal regulations regarding notification of the sponsoring agency in the event an investigator(s) has (have) failed to comply with this policy. The sponsor may take its own action as deemed appropriate, including suspension of funding for the investigator(s), until the matter is resolved.

IV. Reporting Financial Conflicts of Interest.

a. **Sponsoring agency.** SFI that the CIRC determines to be Financial Conflicts of Interest and investigator compliance with a Management Plan, if relevant, will be reported by the RIO to NIH in accordance with agency requirements within 60 days of the original disclosure. Annual updates will also be filed through the NIH's annual reports process.

If the college has failed to manage a Financial Conflict of Interest or an investigator has failed to comply with a management plan, the college is required to complete a retrospective review of the research within 120 days to determine whether the research conducted during the period of noncompliance was biased in its design, conduct, or reporting. If bias is identified, the college must develop a mitigation report outlining a plan of action to eliminate or mitigate the effect of the bias. The results of that determination and the mitigation report must be reported to NIH in accordance with its requirements.

- b. **Public request.** As required by NIH, information on the nature of such Conflicts of Interest will be made available to members of the public by the RIO in response to inquiries specifying the investigator name and the research project in question within 5 business days of receipt of such requests.
- V. **Enforcement.** The college shall establish appropriate mechanisms for enforcement of this policy, which shall provide for sanctions if needed. All relevant regulatory bodies and funding agencies will be promptly informed of any disciplinary sanctions.
- VI. Training. All individuals conducting externally funded activities and meeting the definition of Investigator proscribed in this policy are required to complete all three modules of the Financial Conflict of Interest training on the CITI program website (<u>https://www.citiprogram.org</u>). This website is available to all Rhode Island College faculty, staff and students. Investigators must complete training prior to seeking institutional approval for proposal submission, with a check-off on that form certifying completion. Currently-funded investigators must complete training in advance of submitting the institutional approval form to be awarded renewal or continuation funding. Renewal training

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must be completed every four years or on any occasion in which the college revises its Financial Conflict of Interest policies and procedures in a manner that affects the requirements of Investigators. CITI completion certificates are sent electronically to the Investigator and ORGA. Certificates will remain on file in ORGA

- VII. Disclosure Statement. The College's Financial Conflict of Interest policy and associated disclosure statements are available online at: <u>http://www.ric.edu/orga/policies_coi.php</u>. The *Conflict of Interest Investigator Financial Disclosure Statement* must be completed and submitted as part of the request for institutional approval to submit a proposal. It should be completed by any/all individuals meeting the definition of an investigator on the project. Final assurance and certification of any proposal submission will not be authorized until forms for all investigators are submitted to the RIO. By signing this form, the Investigator certifies that she/he has read the College's Financial Conflict of Interest policy and completed the online Financial Conflict of Interest training. The individual also certifies that she/he either does not have any potential Financial Conflicts of Interest or does have potential Financial Conflicts of Interest and has submitted relevant information to the RIO for preliminary review. In either case, the applicant also declares that she/he will notify the RIO of any change or discovery requiring modification of the above statement.
- VIII. Subrecipients. Rhode Island College is responsible for ensuring that all subrecipients comply with the applicable federal regulations regarding Financial Conflicts of Interest. To this end, the college shall enter a written agreement with each subrecipient that shall specify whether this policy, or the applicable policy of the subrecipient's institution will apply to subrecipient Investigators. Said agreement will specify the timing for reporting of such Financial Conflicts of Interest in compliance with funding agency requirements.

Links:

- 1. NIH source page with links to rules and FAQ: <u>http://grants.nih.gov/grants/policy/coi/</u>
- 2. Federal Register Notice with final rule (August 25, 2011): <u>http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf</u>
- 3. Address to send general FCOI inquiries: FCOICompliance@mail.nih.gov