

COLLEGE of CHARLESTON

OFFICIAL POLICY

8.7.19

**Financial Interest (Conflict of Interest) Disclosure
Policy for Sponsored Projects and Research**

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Policy Statement

These guidelines define general College of Charleston policy and procedures regarding conflicts of interest in relationship to sponsored projects involving research, education, and university service. Their purpose is to protect the credibility and integrity of the College's faculty and staff so that public trust and confidence in the College's sponsored activities is ensured.

Policy Manger and Responsible Department or Office

Director
Office of Research & Grants Administration

Purpose/Reason for the Policy

In accordance with Federal regulations, the College of Charleston has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of a faculty or staff member who is involved in the design, conduct, and/or reporting of a sponsored project or research involving human subjects. Thus, the College requires that these faculty and staff members disclose any significant financial interests that would reasonably appear to be affected by sponsored program activity or human subjects research.

Departments/Offices Affected by the Policy

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Procedures Related to the Policy

Each investigator is required to disclose the following significant financial interests:

- Any significant financial interest of the investigator that would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor; or
- Any significant financial interest of the investigator in an entity whose financial interest would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor.

Regardless of the above minimum requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Each investigator who has significant financial interests requiring disclosure shall complete a Significant Financial Interests Disclosure Form and attach all required supporting documentation. For sponsored research the completed disclosure form must be submitted with the proposal and Pre-Award Routing Sheet to the Office of Research and Grants Administration according to routine College proposal processing procedures. For research involving human subjects, the disclosure must be submitted to the IRB along with the Human Research Review Application. Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted in a sealed envelope marked confidential and accompany the disclosure form and the routing sheet.

As required by Federal regulation, all significant financial interests must be disclosed prior to the submission of a project proposal or Human Research Review Application. Investigators must update financial disclosures during the period of the award as new reportable significant financial interests are obtained.

The Provost, or his or her official designee, shall conduct an initial review of all Financial Interest Disclosure Forms. If the initial determination is made that there may be a potential for conflict of interest covered by this policy, then the disclosure packet will be referred to the College Conflict of Interest Review Committee (CIRC). CIRC members are appointed

by the Provost. The CIRC shall include, at a minimum, three faculty members representing a cross section of academic disciplines and a research administrator. A conflict of interest exists when the CIRC reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The CIRC shall then determine what conditions or restrictions, if any, the institution should impose to manage actual or potential conflicts of interest that arise from disclosed significant financial interests.

Prior to consideration by the CIRC, the investigator, in cooperation with his or her academic department/unit director and dean/cognizant vice president, shall develop and present to the CIRC a Conflict of Interest Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest. (To assist faculty and staff in this process, the College has developed "Guidelines for the Development of a Conflict of Interest Resolution Plan and the Preparation of a Memorandum of Understanding.") At a minimum the resolution plan shall address such issues as:

- Public disclosure of significant financial interests;
- Review of the research protocol by independent reviewers; and
- Monitoring of the research by independent reviewers.

Where it deems appropriate, the CIRC shall review the resolution plan, modify it or add conditions or restrictions as necessary, and approve or disapprove it. Modifications, conditions, and restrictions that the CIRC may consider include, but are not limited to, the following:

- Modification of the research/project plan;
- Disqualification of the investigator from participation in all or a portion of the project;
- Divestiture of the investigator's significant financial interests; and
- Severance of relationships that create actual or potential conflicts of interest.

If the CIRC determines that imposing the above referenced conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the CIRC may recommend that, to the extent permitted by Federal regulations (U.S. Public Health Service [PHS] policy, for instance, does not permit such an action), the research go forward without imposing such conditions or restrictions. In these cases, the Provost shall make the final decision regarding resolution.

The approved resolution plan shall be incorporated into a Memorandum of Understanding between the College of Charleston and the investigator that details the conditions or restrictions imposed upon him or her in the conduct of the project or research in the relationship with the sponsor. The Memorandum of Understanding shall be signed by the investigator, the department chair/unit director, the dean/cognizant vice president, and, on behalf of the College, the Provost. Actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these Guidelines and all

required reports regarding the conflict of interest submitted to the sponsor prior to expenditure of any funds under an award. (For example, PHS requires the College to report to the PHS Awarding Component the existence of a conflicting interest [but not the nature of the interest or other details] found by the College and to assure that the interest has been managed, reduced, or eliminated. The National Science Foundation [NSF] only requires the College to report conflicts that cannot be satisfactorily managed, reduced, or eliminated.)

Records of investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the Office of Research and Grants Administration until three years after the later of the termination or completion of the award to which they relate or the resolution of any government action involving those records.

When an investigator violates this policy or the terms of the Memorandum of Understanding, the CIRC shall recommend sanctions that may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. If the violation results in a collateral proceeding under College policies regarding misconduct in research and scholarship, then the CIRC shall defer a decision on sanctions until the misconduct in research and scholarship process is completed. The CIRC's recommendations on sanctions shall be presented to the investigator's dean/cognizant vice president who, in consultation with the Provost, shall enforce any disciplinary action. In addition, the College shall follow Federal regulations regarding the notification of the sponsoring agency in the event an investigator fails to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the investigator until the matter is resolved.

Collaborators/subrecipients/subcontractors from other academic or not-for-profit institutions must either comply with this policy or provide a certification from their institutions that they are in compliance with Federal policies regarding investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies. Subcontractors from commercial firms need not make a certification, except when the prime award is from the U.S. Public Health Service. The PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding investigator significant financial interest disclosure and that its portion of the project is in compliance with company policies.

Related Policies, Documents or Forms

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Review Schedule

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| Issue Date: Month/Date/Year | Next Review: Month/Date/Year |
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