

NUMBER: RSCH 1.06 (REVISED)
SECTION: Research
SUBJECT: Disclosure of Financial Interests and Management of Conflicts of Interest
Related to Sponsored Projects (Research)
DATE: January 31, 2014
Policy for: Columbia and Regional Campuses
Procedure for: Columbia and Regional Campuses
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I. Policy

The university has published high standards for faculty conduct, including the conduct of research, in the University of South Carolina (USC) Faculty Manual and its Policies and Procedures. All USC Investigators are expected to carry out research consistent with these standards.

Even when these high standards have been met, conflicts of interest or perceptions of conflicts may still occur when there is a convergence of an Investigator's private interests with his or her research interests, such that an independent observer might reasonably question whether the Investigator's professional actions or decisions are improperly influenced by considerations of personal financial gain. Such conflicts are common in modern research universities and do not impugn the character or actions of any individual.

Although the university does not require Investigators to disclose their personal financial interests as a matter of routine, the university may be obligated by external requirements, or may establish such requirements on a program by program basis, to require disclosure processes under circumstances specified in Section I.B. of this policy. Such disclosure processes are the most widely accepted method for identifying and managing actual or potential conflicts of interest related to sponsored projects in public institutions.

Therefore, it is the policy of the university that any Investigator (that is, any university employee responsible for the design, conduct, or reporting of a sponsored project at the university) may be required to disclose significant personal financial interests related to his/her institutional responsibilities pursuant to circumstances specified by this policy.

When the university reasonably determines that the significant financial interest could directly and significantly affect the design, conduct or reporting of the research, the university will take steps either to manage or to eliminate any financial conflicts of interest.

This policy supplements, but does not supplant, the University Policy ACAF 1.50 Outside Professional Activities for Faculty.

A. Purpose

This policy is intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under externally sponsored grants, contracts and cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

B. Scope

This policy shall apply automatically to research projects sponsored by the U.S. Public Health Service, including the National Institutes of Health, and the National Science Foundation. As described below, the university may elect to apply the disclosure requirements of this policy to other externally sponsored projects and certain university-managed programs. Application of this policy will be expanded to other extramural sponsors as necessary to comply with official requirements subsequently imposed by those sponsors. Updated information regarding specific institutional and sponsoring agency requirements can be located at <http://orc.research.sc.edu>.

1. Federal Disclosure Requirements:

This policy implements federal requirements pertaining to “Objectivity in Research for which Public Health Service Funding is Sought” promulgated by the U.S. Public Health Service (PHS), which includes the National Institutes of Health (NIH), and which are published in 42 CFR Part 50 and 45 CFR Part 94. This policy also implements federal requirements contained in the National Science Foundation’s “Investigator Financial Disclosure Policy.” Both agencies require the university to maintain an appropriate written policy on conflict of interest disclosure as a condition for receiving federal grants. These federal requirements, as implemented in this policy, are applicable to all proposals for extramural awards submitted to these two federal agencies.

2. Other Sponsors Programs and Projects:

The university may elect to apply the disclosure requirements of this policy to all or selected other externally funded programs. The applicability of this policy to such programs requires the joint approval of the vice president for research and the provost.

When individual sponsored projects are not covered under B.1., investigators may be required by a sponsoring agency or the Office of Sponsored Awards Management (SAM) to disclose financial interests that are related to a specific project. Such disclosures are handled according to the procedures set forth in this policy.

3. Voluntary Disclosure:
On occasion, Investigators may have questions about whether certain financial interests or relationships whose disclosure is not required under the terms of this policy, but may nevertheless appear to constitute an actual or potential conflict of interest with respect to a sponsored project. In such cases, Investigators may choose voluntarily to apply the disclosure requirements of this policy to the sponsored project in question.

II. Procedures

A. Disclosure of Financial Interests

When an Investigator has a significant financial interest that is related to his/her institutional responsibilities as defined below, a formal disclosure describing that interest is required. The absence of a significant financial interest also requires a disclosure stating that no outside interests exist.

This reporting responsibility is separate from an Investigator's ongoing duty to update financial disclosures at least annually and as any new significant financial interests is recognized throughout the period of the sponsored award.

B. Definitions

1. Investigator
A principal investigator, project director, co-investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of sponsored research (project) results, including collaborators and consultants.
2. University Conflict of Interest Committee (COIC)
The Committee appointed by the Provost in accordance with University Policy ACAF 1.50 Outside Professional Activities for Faculty to review disclosures and relevant features of the sponsored project(s) and, on the basis of the review, to recommend to the Reviewing Official any modifications necessary to manage any financial conflicts of interests related to the project.
3. Financial Interest
Anything of monetary value, whether or not the value is readily ascertainable (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, equity interests, intellectual property rights etc.).
4. Significant Financial Interest

A Financial Interest held by an Investigator, or the Investigator's spouse or dependent children that reasonably appear to be related to the Investigator's Institutional Responsibilities and that consists of one or more of the following:

- a. Remuneration including, but not limited to salary, consulting fees, honoraria, and paid authorship received from a publicly traded company during the 12-month period preceding the date on which an Investigator is making a disclosure, and/or an equity interest (e.g. stock, stock options or other ownership interest) held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the equity interest as of the date of disclosure, exceeds \$5,000; or
- b. Remuneration received from a non-publicly traded company during the 12-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000; or
- c. Any equity interest in a non-publicly traded company or business, regardless of value; or
- d. Intellectual property rights and interests (e.g. patents and copyrights), upon receipt of income related to such rights and interests.
- e. Any reimbursed travel or travel expenses paid on an Investigator's behalf related to his/her institutional responsibilities, including circumstances when the exact monetary value of the travel is not readily available. This requirement does not apply to travel that is reimbursed by a Federal, state or local government, an institution of higher education, an academic medical center or research institute that is affiliated with an institution of higher education.

Significant Financial Interest does not include:

- a. An Employee's salary or royalties received from the university and/or the South Carolina Research Foundation; or
- b. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or an institution of higher education; (Note: Such income may be subject to restrictions and reporting requirements under other institutional and state policies.) or
- c. Income from service on panels for a federal, state or local government agency or institution of higher education.

5. Institutional Responsibilities

An Investigator's professional obligations carried out on behalf of the university, involving the Investigator's expertise. Examples include activities such as research, research consultation, teaching, professional practice, participation in purchasing decisions, evaluating products on behalf of the university, university committee memberships, and service on panels such as institutional review boards or regulatory oversight committees.

6. Financial Conflict of Interest

When applied to an Investigator, Financial Conflicts of Interest occur in situations in which an Investigator's Financial Interest compromises, or could appear to bias, his or her professional judgment regarding the design, conduct or reporting of research, or if such Financial Interest could directly and significantly affect the design, conduct or reporting of research.

7. University Reviewing Official

The official designated by the university to solicit and review disclosures of significant financial interests and reasonably determine whether an Investigator's reported financial interest is related to the sponsored research and, if so related, whether the significant financial interest is a financial conflict of interest.

C. Disclosure Requirement

For each sponsored project application covered under the terms of this policy, each Investigator must fully disclose all Significant Financial Interests (and those of the Investigator's spouse and dependent children) related to his/her institutional responsibilities no later than the time of the application for the sponsored research/project. All Investigators participating in sponsored research covered under the terms of this policy also must file an updated Disclosure of Financial Interests at least annually or within thirty days of discovering or acquiring a new significant financial interest.

D. Disclosure and Update Form(s)

When an Investigator has a significant financial interest (SFI) that is related to his/her institutional responsibilities, as defined above, a completed disclosure form detailing that interest is required. In the absence of an SFI, the Investigator must submit a negative disclosure statement using the specified reporting form. Additionally, it is an investigator's ongoing duty to update financial disclosures annually and as new significant financial interests are recognized throughout the period of the award. Disclosure and Update form(s) will be designed by the Reviewing Official who, in consultation with the COIC, will determine the appropriate level of detail necessary for review. The Disclosure and Update form(s) must:

1. Indicate whether the Investigator (including his/her spouse or dependent children) has any significant financial interests related to his/her institutional responsibilities;
2. Provide the name of each entity in which the Investigator has a significant financial interest and the type of the financial interest (income, equity, management position or intellectual property);
3. Indicate whether the entity in which the Investigator has a significant financial interest is a proposed subcontractor, consortium member, supplier of goods, lessor, or otherwise involved with the sponsored project(s);
4. Indicate whether the entity in which the Investigator has a significant financial interest might manufacture or commercialize any drug, vaccine, device, procedure or any other product involved in or that will predictably result from the sponsored project(s);
5. Disclosure and Update form(s) may provide the Investigator with a direct opportunity to indicate whether or not he or she believes the project(s) could directly and significantly affect the related financial interest(s) he or she is reporting; and
6. Provide notice to the Investigator that the disclosure will be open to public inspection and include a Privacy Act Notice substantially as follows: The principal purpose for requesting the information on this form is to comply with university policy and federal regulations regarding disclosure of any financial interests that would reasonably appear to be affected by the conduct of a sponsored project. Provision of the information is mandatory if you want to submit a proposal for support of a project covered by the terms of this policy. This information will be used to implement the USC Policy on Disclosure of Financial Interests and Management of Conflicts of Interest Related to Sponsored Projects. The information may be released or transmitted to the sponsor, including federal agency representatives, and, according to state law, may also be released to the public upon request.

E. Review of Disclosures

The Disclosure shall be reviewed by the Reviewing Official and/or the COIC to determine whether any reported significant financial interest: could be affected by the funded research; or is an entity whose financial interest could be affected by the sponsored research/project.

A financial conflict of interest exists when the university through its Reviewing Official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the sponsored research/project.

A direct impact occurs when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator has a financial interest, or when the entity is a proposed subcontractor or participant in the project. A significant impact on the financial interest is one which will materially affect the value of the entity, its earnings or the sales of its products, or the entity is a proposed subcontractor or participant in the project.

Based on information provided in the Disclosure, the Reviewing Official and/or the COIC may determine that there is no reasonable basis on which to conclude that a project could affect the financial interest and/or that the financial interest is not likely to directly and significantly affect the design, conduct, or reporting of the project. In this case, a record should be made of the Reviewing Official's or Committee's action and the project can proceed without further review.

In the event that the university Reviewing Official reasonably concludes that a project could have an impact on the financial interest and that the financial interest could affect directly and significantly the design, conduct or reporting of the project, the Disclosure and appropriate documentation shall be forwarded to the COIC. The COIC, working with the Reviewing Official, will make a final decision about the appropriate actions that are necessary to manage the conflict of interest. The same review process takes place when an Investigator files an Update form reporting a new significant financial interest.

F. Management or Elimination of Conflicts of Interest

When it is reasonably determined that an Investigator has financial interests that could directly and significantly affect the design, conduct or reporting of the research/sponsored project, the University Reviewing Official and the COIC will recommend implementing a plan and procedures to manage the conflict of interest in order to minimize the effect of the related Significant Financial Interest(s) on the design, conduct, or reporting of the sponsored project(s). Investigators also may be asked to make recommendations about how to manage the conflict of interest. Examples of conditions or restrictions that may be imposed to manage or eliminate conflicts of interest include:

1. Public disclosure of financial conflicts of Interest(s) when presenting or publishing research;
2. For projects involving human subject research, disclosure of financial conflicts of interest directly to subjects;
3. Monitoring of the project by independent reviewers capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from financial conflicts of interest;
4. Modification of the research or project plan;

5. Disqualification of Investigator(s) from participation in all or a portion of the project;
6. Reduction or elimination of the financial interest (e.g. sale of an equity interest);
or
7. Severance of relationships that create financial conflicts.

Alternatively, the Reviewing Official and COIC may recommend that the project not be undertaken by the university if it is determined that the conflicts cannot be managed satisfactorily.

The review of the Disclosure(s) and adoption of conditions or restrictions to manage or eliminate the conflict of interest must be completed prior to expending funds made available under the sponsored award. When required, a report of the existence of a conflict of interest and assurance that it has been managed, reduced or eliminated, must be submitted to the sponsoring agency.

G. Sanctions

Failure to file a complete Disclosure of Financial Interest Form or Update Form, or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be grounds for disciplinary action pursuant to the relevant university policies related to faculty conduct or other applicable employee disciplinary policies.

In addition, federal regulations may require reports to the federal sponsor of any information which may show a violation of university policy. Sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of significant financial interests related to federally sponsored projects.

H. Responsibilities and Administration

The provost, vice president for research and deans within their respective areas of responsibility, shall implement this policy. Implementation shall be monitored by the vice president for research or designee, in consultation with the provost.

Records regarding Disclosures, Reviewing Official's determinations, COIC recommendations, and university actions regarding management of a conflict of interest must be retained for three years beyond the termination or completion of an award, or until resolution of any action by the sponsor involving the records, whichever is longer.

Implementation of this Policy shall include compliance with applicable sponsor regulations governing institutional responsibilities, certification of compliance, reporting requirements and other duties required under the specific sponsor's regulations.

III. Related Policies

See also:

University Policy ACAF 1.50 Outside Professional Activities for Faculty

IV. Reason for Revision

This policy was revised to include certain projects that are required to provide disclosure of related financial interest according to accepted university procedures.