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Policy Name and Number: **Financial Conflict of Interest (FCOI) on Sponsored Programs (S4.5)**

Policy Developer(s): Office of Sponsored Programs

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Body

POLICY

Investigators are prohibited from using their positions for purposes inconsistent with objectivity in research and professional integrity. When there is a conflict between John Carroll University ("the University") policy/procedure and sponsor requirements, the more restrictive policy/procedure applies.

PURPOSE

The Department of Health and Human Services published [Subpart F—Promoting Objectivity in Research](#) to establish standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from investigator financial [conflicts of interest](#) (FCOI) or [significant financial interests](#) (SFI). John Carroll's policy will be extended to all externally sponsored projects. The full notice can be found by visiting the [Electronic Code of Federal Regulations'](#) webpage.

While the investigators of John Carroll University recognize that their primary professional obligation is to John Carroll University, they must be alert to the possibility that outside arrangements, whether they be financial interests or employment relationships, may compromise their objectivity as teachers, researchers, and administrators. This rule pertains to both full-time and part-time investigators. To avoid any such possible conflict of interest, or the appearance of a conflict of interest, in the conduct of grant or contract activities, the safeguards outlined in this document are hereby established, and are consistent with federal regulations [45 CFR 75 Uniform Administrative Requirements, Cost Principles and Audit](#)

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

[Requirements for HHS Awards](#) and [2 CFR 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards](#).

SCOPE

All individuals involved with the administration and conduct of sponsored award activities, including faculty, staff and students, must comply with this policy. As defined below, *investigator* includes any person at the University who is responsible for the design, conduct, or reporting of research or educational activities funded, or proposed for funding, by an external sponsor, which can include sub-recipient investigator(s), students, and consultants, if applicable. For purposes of disclosing financial interests, *investigator* includes the investigator's spouse and dependent children.

PROCEDURES

Federal regulations require institutions to have policies and procedures in place to ensure that investigators disclose any significant financial interest that may present a conflict of interest in relationship to externally sponsored projects. Such disclosures must be made prior to the submission of a proposal for funding, and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced or eliminated prior to award or acceptance of an award. The director of the Office of Sponsored Programs (OSP) will manage this process, assure adherence to the policy and act as a liaison between federal agencies and the PI(s).

A. Disclosure Requirements

1. What must be disclosed? Each investigator shall disclose all significant financial interests:
 - a. That would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
 - b. In entities whose financial interests would reasonably appear to be affected by such activities.
2. What is covered? "Significant financial interests" means anything of monetary value, including but not limited to:
 - a. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes 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

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

determined through reference to public prices or other reasonable measures of fair market value.

b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option or other ownership interest).

c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

d. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation. The investigator is not required to disclose travel that is 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 institute that is affiliated with an institution of higher education.

e. The investigator is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization or corporation either funding a sponsored project or providing goods and services under a sponsored project on which the investigator is participating in any capacity.

The term does not include:

a. Salary, royalties, or other remuneration from John Carroll University; Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.

b. Income from investment vehicles, such as mutual funds and 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 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.

d. Income from service on advisory committees or review panels for a federal, state or local government agency, 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.

3. How do I disclose my interests?

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

- a. All investigators must disclose their significant financial interests utilizing the Financial Conflict of Interests on Sponsored Programs form and by attaching any required supporting documentation. The completed form and attachments are to be submitted prior to proposal submission to the Office for Sponsored Programs (OSP).
 - b. In accordance with federal regulations, a complete disclosure must be made by investigator(s) prior to the submission of the proposal and annually thereafter during the period of the award.
 - c. A complete disclosure must be made within 30 days of discovering or acquiring a new SFI at any time during the period of the award.
 - d. Management Plans for potential conflicts of interest will be incorporated into a signed agreement that is executed between the investigator(s), the Provost/Academic Vice President, and the department chair prior to making any expenditures of sponsored project funds.
 - e. The National Science Foundation only requires the University to report conflicts which cannot be satisfactorily managed or eliminated.
4. What do I need to fill out prior to submitting my grant?
- a. The Financial Conflict of Interests on Sponsored Programs form with all corresponding documentation must be filled out, signed and submitted to OSP.
 - b. Each investigator must complete training prior to engaging in research related to any Public Health Service (PHS)-funded grant or contract and at least every four years, and immediately when a PHS-funded investigator is new to John Carroll.
 - c. John Carroll uses CITI program for its FCOI training. Any investigator applying for PHS funding must complete the training prior to award acceptance. Please visit [John Carroll's Office of Sponsored Programs CITI Training](#) webpage for further instructions.
 - d. FCOI training through CITI must also be completed immediately, if:
 - JCU revises its FCOI policy so that it affects requirements of the principal investigators
 - An investigator is new to John Carroll University
 - An investigator is found to not be in compliance with the policy or applicable management plan
 - e. The National Institutes of Health policies related to SFI and FCOI can be found at <https://grants.nih.gov/grants/policy/coi/index.htm>

B. Designated Official Review

- I. If the director of the Office for Sponsored Programs, or their designee, determines that the potential for more than a remote or minimal conflict of interest may exist, that person shall schedule a meeting with the Vice Provost for Academic

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

Affairs review the proposal and the disclosures. The Vice Provost for Academic Affairs will review each disclosure form as submitted in consultation with other university officials, as appropriate (e.g., department chair, academic dean, Academic Vice President, Vice President for Finance and Administration, Legal Affairs office). The Vice Provost for Academic Affairs may determine that no further action is necessary.

2. If the Vice Provost for Academic Affairs determines that further review is necessary, a meeting will be convened with the investigator and any other appropriate university officials to discuss the disclosure. Additional information may be requested of the investigator. If, after discussion, the Vice Provost for Academic Affairs determines that appropriate conditions and/or restrictions are necessary to manage, reduce, or eliminate a conflict, such conditions and/or restrictions will be imposed.

3. OSP will work with Legal Affairs and the principal investigator to develop a Management Plan that details proposed steps that will be taken to reduce or eliminate the potential conflict of interest. Methods adopted in the plan may include one or more of the following:

- a. public disclosure of the significant financial interests in publications or to research staff/students
- b. divestiture of financial interests
- c. monitoring of research by independent reviewers
- d. modification of the research plan
- e. disqualification from participation in all or a portion of the research
- f. severance of relationships that create actual or potential conflicts of interest.

4. An investigator who believes the determined course of action is an inappropriate resolution may appeal to the Provost/AVP or their designee. The decision of the Provost/AVP shall be final.

5. Violations of this policy (such as willful concealment of financial interests) or of the terms of the Management Plan may result in sanctions being imposed upon the violating individual. Employees in violation of this policy shall be subject to the appropriate disciplinary action under the applicable University policies, up to and including, termination of employment.

C. Reporting to NIH: Initial, annual, and revised FCOI reports will be submitted to NIH as required by the regulation:

1. Prior to the expenditure of funds.
2. Within 30 days of identification of a new SFI.
3. Within 60 days of identification of an investigator who is newly participating in the project.
4. Within 60 days for new, or newly identified, FCOIs for existing investigators

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

5. At least annually to provide the status of the FCOI and any changes in the management play through completion of the project.
6. Following any retrospective review to update a previously submitted report, if needed.

D. Requirements for Subaward/Subcontract/Consultant

1. In accordance with 42 CFR Part 50 Subpart F and 45 CFR Part 94, all investigators and key research personnel participating in a University sponsored project through a Subaward/Subcontract/Consultant Agreement must comply with written policies relating to the disclosure of Significant Financial Interests which may constitute or may be perceived to constitute a Financial Conflict of Interest affecting the design, conduct or reporting of the project.
2. If a Subaward/Subcontract/Consultant Agreement is being issued under a prime award from HHS, PHS, NIH or other non-federal agency that applies the PHS FCOI regulations, there must be verification that the Subrecipient/Subcontractor/Consultant has a policy that complies with the ~~2011~~ PHS FCOI regulations:

- Check the FDP Clearinghouse (http://sites.nationalacademies.org/PGA/fdp/PGA_070596) to see if the Subrecipient/Subcontractor/Consultant is registered as compliant; or
- Obtain an endorsed letter or certification from the Subrecipient/Subcontractor/Consultant verifying and attesting that it has a policy that complies with the 2011 PHS FCOI regulations; or
- Request that the Subrecipient/Subcontractor/Consultant complete the JCU Subrecipient Financial Conflicts of Interest Certification Form.

If the Subrecipient/Subcontractor/Consultant does not have a financial disclosure policy consistent with 42 CFR Part 50 Subpart F and cannot provide such certification, the investigators will be subject to the University financial conflicts of interest policy for disclosing significant financial interests that are directly related to the subrecipient's involvement in the sponsored project.

E. Subrecipient Reporting and Notification

1. All subrecipients must report discovery of a FCOI to John Carroll as the prime within 30 days. PHS requires that all subcontractors, including commercial firms, follow the above guidelines.
2. The University recognizes its obligation to report information emanating from the subrecipient FCOI process to sponsoring agencies, and will provide the necessary information to those agencies in a manner, format, and level of detail consistent with the sponsor's requirements for such reporting.

F. Financial Conflict of Interest is Found—Next Steps

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

1. **Sponsor Regulations and Notification:** The University recognizes its obligation to report information emanating from the University's FCOI process to sponsoring agencies, and will provide the necessary information to those agencies in a manner, format, and level of detail consistent with the sponsor's requirements for such reporting. The Director of Sponsored Programs will review the sponsoring agency's reporting requirements to ensure the appropriate information is submitted.
2. **Retrospective Review:** A retrospective review and mitigation report will be submitted to the federal agency within 120 days of determination of non-compliance for SFIs not disclosed at the time of the proposal. The review and mitigation report will be signed by the Provost, Principal Investigator, Department Chair, and Vice President for Finance and Administration, and submitted to the federal agency prior to making any expenditures of sponsored project funds.
3. **Review Meeting:** The Provost, Vice Provost for Academic Affairs, legal affairs, and OSP will meet within 60 days to determine if any disciplinary action is necessary, establish a ruling and set forth a corrective action plan which will then be reported to the sponsor within 120 days, in accordance with policy 42 CFR 50.605(a)(3).
4. **Publications/Sponsored Programs/Presentations:** If any researcher is involved in a finding of non-compliance with the FCOI policy, especially where it involves evaluation of the safety of a drug, medical device or treatment, the PI will retroactively request an addendum to any published research or presentations on such research. The PI must also make the FCOI clear in any dissemination of research findings going forward.
5. **Sponsor Reporting:** The PHS requires the University to report to the PHS Awarding Component the following:
 1. Project director/Principal investigator
 2. Grant/Contract number
 3. Name of investigator with the Financial Conflict of Interest (FCOI)
 4. Whether the FCOI was managed, reduced, or eliminated
 5. Name of the entity with which the investigator has a FCOI
 6. Nature of FCOI (e.g. equity, consulting fees, travel reimbursement, honoraria)
6. **Federal Regulations:** The University shall follow federal regulations regarding the notification of the sponsoring agency in the event an investigator has failed to comply with this policy. The sponsor may take its own action as it deems

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

appropriate, including the suspension of funding for the investigator until the matter is resolved.

7. **PHS Notifications:** PHS requires that the institution notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component in cases where FCOI or SFI introduce bias into the research. The report will address the impact of the bias on the research project and the actions the institution has taken, or will take, to eliminate or mitigate the effect of the bias.

G. Records Retention

1. The Vice Provost for Academic Affairs will maintain records of all financial disclosure statements filed and all actions taken to resolve actual or potential conflicts for at least three years after the termination or completion of the award to which those records relate or until resolution of any government activity related to those records. This includes other dates as specified in 45 CFR 75.361, where applicable.
2. Reports will also be kept for a period of 10 years past the submission of a final expenditure report of any PHS-funded project, or upon the resolution of any government action involving those records, whichever comes first.
3. OSP will also submit annual reports to NIH and request annual disclosures from faculty and subrecipients to be included in these reports.

H. Public Accessibility

1. John Carroll's FCOI policy is publicly available on the institution's website.
2. Information concerning identified FCOIs held by senior/key personnel must be made publicly available prior to the expenditure of funds. The publicly accessible information:
 - a. Will include the minimum elements as provided in the regulation 42 CFR 50.605(a)(5)(i)-(iv)
 - b. Be posted on JCU's publicly available website which will be updated annually.
 - c. Be made available within five calendar days of receipt of a written request.
 - d. Be updated within 60 days of a newly identified FCOI
 - e. Remain available for three years from the date the information was most recently updated.

I. Related Required Disclosures

1. **Disclosures in Public Presentations:** University faculty members or administrators must disclose their FCOI in each public presentation of the results of the research. Any previously published presentations must be amended to disclose the conflict if it applies to those research activities resulting in a presentation.

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

2. Disclosures When Serving on University Committees or Boards: University faculty members or administrators must temporarily excuse themselves from any university committee or review process that is considering an activity in which they have a significant financial interest.
3. Disclosures When Involved with Technology Transfer: University faculty members or administrators seeking to transfer university-developed or supported technology through patents or licensing to a business in which the faculty member or administrator has a financial interest, must disclose such interests in writing to the Vice Provost for Academic Affairs and seek approval prior to commencing such efforts.
4. Disclosures of Other Interests: University faculty members or administrators engaged in sponsored research must disclose any family connections to organizations funding a sponsored project or in an organization from which goods/services will be obtained under the sponsored project.
5. Sanctions: All members of the University community to whom this policy applies are expected to comply fully and promptly with all requirements. Failure to file, intentionally filing an incomplete or erroneous or misleading disclosure form, or failing to provide additional information upon request may be grounds for disciplinary action, up to and including termination of employment, as well as the basis for other penalties applicable under federal or state law.

DEFINITIONS

- A. **Investigators**: These are principal investigators and “any person responsible for the design, conduct, or reporting” of projects funded or proposed for funding. Investigators may include faculty members, administrators, staff members and, in certain cases, students. For purposes of disclosing financial interests, *investigator* includes the investigator’s spouse and dependent children.
- B. **Significant Financial Interest**: “anything of monetary value, including but not limited to” salary or other payments for services, e.g., consulting fees or honoraria (when aggregated for the investigator, spouse and dependent children) expected to exceed \$5,000 in the next twelve months; an equity interest, e.g., stock, stock option, other ownership interests (when aggregated for the investigator, spouse and dependent children) with a fair market value over \$5,000 or which represent more than a 5% ownership in any single entity; intellectual property rights (e.g., patents, copyrights and royalties from the rights).

The following are NOT considered “significant financial interests” for purposes of required disclosure:

- salary, or stipends from the University other than research funding;
- income from seminars, lectures, or teaching sponsored by public or nonprofit entities;

S4.5 Financial Conflict of Interest (FCOI) on Sponsored Programs

- income from service on advisory committees or review panels for public or nonprofit entities;
- any ownership interest in an institution applying for funding under the Small Business Innovation Research Program or the Small Business Technology Transfer Program.

C. **Conflict of Interest:** A Conflict of Interest exists when the University's designated officials reasonably determine that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the sponsored project.

CROSS REFERENCES

A. [University Policies](#), including but not limited to

1. Sponsored Research Policies
2. Bank Account Reconciliation
3. [General University Conflict of Interest Policy](#)

B. Federal Regulations, Statement, and Mandates

1. [45 CFR 75.112](#)
2. [45 CFR 75.327\(c\)\(1\)](#)
3. [2 CFR 200.112](#)
4. [2 CFR 200.318](#)
5. [20 U.S.C. 1001\(a\)](#)
6. [42 CFR 50.605\(a\)\(3\)](#)
7. [45 CFR 75.361](#)
8. [HHS Grants Policy Statement](#)
9. [HRSA Legislative Mandates in Grants Management for FY 2018](#)
10. [NIH Grants Policy Statement](#)
11. [NSF Proposal and Award Policies and Procedures Guide](#)

This policy will next be reviewed **five years** from the approval date/date of last review.