



Policy: Financial Conflict of Interest (FCOI) on Sponsored Programs	Policy No: S4.5
Policy Developer(s): Office of Sponsored Research	Original Date: May 18, 2018
Last Review Date:	Approval Date: October 17, 2019

- I. **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.

- II. **PURPOSE:** Consistent with federal regulations [45 CFR 75 Uniform Administrative Requirements, Cost Principles and Audit Requirements for HHS Awards](#) and [2 CFR 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards](#) designed to promote objectivity in research, the University establishes this conflict of interest policy for all faculty and other University personnel engaged in the design, conduct or reporting of sponsored research and educational activities, including consulting work (collectively, “sponsored projects”).

- III. **SCOPE:** All individuals involved with the administration and conduct of sponsored award activities, including faculty, staff and students, must comply with this policy.

- IV. **PROCEDURES:** This policy is intended to inform investigators of the regulations, the University’s policy, and the investigator's obligations to disclose [significant financial interests](#). Once such interests are disclosed, the University must decide whether the disclosed financial interests create a [conflict of interest](#) that could bias the design, conduct or reporting of sponsored projects. If so, the University must manage, reduce, or eliminate the conflict prior to the expenditure of any funds under an award.
 - A. **Disclosure Requirements**
 1. When Submitting a Proposal for Sponsored or Funded Research or Other Educational Activity: Whenever a contract or grant proposal is submitted to any sponsor, principal investigators and any named key personnel must file a Disclosure of Financial Interests Form with the Office of Sponsored Research. Each investigator must disclose all significant financial interests, including those of the investigator’s spouse and dependent children: a. that would reasonably appear to be affected by the research or educational activity for which funding is sought; or b. in entities whose financial interests would reasonably appear to be affected by the proposed research or educational activity.
 2. When Financial Interests Change: Each disclosure form must be updated within 30 days if the investigator becomes aware of new reportable significant financial interests.
 3. Annual Disclosure: Each disclosure form must be updated annually if the funded project is an ongoing one.

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B. Designated Official Review

1. The Associate Academic Vice President will review each disclosure form as submitted in consultation with other university officials, as appropriate (e.g., department chair, academic dean, academic vice president, Executive Vice President/CFO, Legal Affairs Office). The Associate Academic Vice President may determine that no further action is necessary.
2. If the Associate Academic Vice President 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 Associate Academic Vice President determines that appropriate conditions and/or restrictions are necessary to manage, reduce, or eliminate a conflict, such conditions and/or restrictions will be imposed (“the management plan”). Examples of conditions or restrictions in a management plan include, but are not limited to:
 - 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.
3. An investigator who believes the determined course of action is an inappropriate resolution may appeal to the Provost/AVP or their designee.
4. The Associate Academic Vice President 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.

C. Subaward/Subcontract/Consultant FCOI: 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.

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 University 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

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disclosing significant financial interests that are directly related to the subrecipient's involvement in the sponsored project.

- D. 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 Research will review the sponsoring agency's reporting requirements to ensure the appropriate information is submitted.

Management plan reports to PHS awarding components will include at a minimum the following elements:

- Sponsor Project Number or identifier
- PD/PI or contact PD/PI
- Name of Investigator with the financial conflict of interest
- Name of Entity with which the Investigator has a financial conflict of interest
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- Value of the financial interest (dollar ranges are permissible):
 - \$0 - 4,999
 - \$5,000 - \$9,999
 - \$10,000 - \$19,999
 - \$20,000 - \$39,999
 - \$40,000 - \$59,999
 - \$60,000 - \$79,999
 - \$80,000 - \$100,000
 - Over \$100,000 (document in increments of \$50K)
 - Value cannot be readily determined
- A description of how the financial interest relates to the funded research, and the basis for the institution's determination that the financial interest conflicts with such research
- A description of the key elements of the management plan, including the following:
 - 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 the 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.
 - Other information as needed.

E. Related Required Disclosures

1. 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.
2. 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

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Associate Academic Vice President and seek approval prior to commencing such efforts.

3. 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.

F. 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.

V. 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;
- 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.

VI. 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)

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3. [2 CFR 200.112](#)
4. [2 CFR 200.318](#)
5. [HHS Grants Policy Statement](#)
6. [HRSA Legislative Mandates in Grants Management for FY 2018](#)
7. [NIH Grants Policy Statement](#)
8. [NSF Proposal and Award Policies and Procedures Guide](#)

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