Policy Name and Number:
(S4.5)

Policy Developer(s): Office of Sponsored Research

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Approval Date: June 16, 2022

Contact Person for Website: Director of Sponsored Programs

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.

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 University has revised its policy on financial conflicts of interest in accordance with the regulations (as of the most recent clarification from December 1, 2020)

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.

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.

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.

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.

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.

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).

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.

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)

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

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.

A. 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.
B. 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.
C. OSP will also submit annual reports to NIH and request annual disclosures from faculty and subrecipients to be included in these reports.

Remain available for three years from the date the information was most recently updated.

A. 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.

B. 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.

C. 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 Academ Discl