



Financial Conflict of Interest in Research Policy

Johnson & Wales University (JWU) employees and, as may be required by agreement or policy, agents, consultants, representatives, and other affiliated individuals will strive to safeguard the university's financial, legal, and reputational standing and their own credibility and reputations, by promoting objectivity while engaged in research activities.

JWU's Procedures for Identifying and Addressing Financial Conflict of Interest in Research (the "Procedures"), which are based on federal regulations published at [42 CFR Part 50, Subpart E](#), are intended to honor that commitment through the management of financial conflicts of interest (FCOIs) that may arise during research activities supported by federal agencies including, without limitation, the National Science Foundation (NSF) and the U. S. Department of Health & Human Services (HHS), which includes the Public Health Services' Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Many private foundations also require their grantees to abide by the regulations cited above. Unless otherwise directed by law or university policy, individuals employed by or affiliated with JWU who intend on seeking funding from, or who are engaged in research funded by, such foundations will also be required to follow the Procedures.



Financial Conflict of Interest in Research Procedures

Terms and Authority

With the exception of terms defined in these Procedures, capitalized terms are defined in [42 C.F.R. § 50.603](#) and elsewhere in the [Public Health Services \(PHS\) FCOI regulations](#).

If [Research](#) is supported by a non-PHS agency or organization with its own requirements governing disclosure, management, and reporting of financial conflicts of interest, and if those requirements are not specifically addressed in these Procedures, then the more restrictive requirements must be followed unless otherwise required by law, university policy, or specific award provisions.

Investigator Responsibilities

Learning/Training

1. Prior to seeking or engaging in any federally sponsored [Research](#), every [Investigator](#) must review and become familiar with JWU's [FCOI](#) Policy and [FCOI regulations](#).
2. Prior to seeking or engaging in any federally sponsored [Research](#), every [Investigator](#) must successfully complete the following courses [or other federally compliant courses approved by the Institutional Official, whose responsibilities are described at [42 C.F.R. §50.604\(d\)](#)] through the [Collaborative Institutional Training Initiative \(CITI\)](#):
 - a. Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (ID 15070)
 - b. Institutional Responsibilities as They Affect Investigators (ID 15072)These courses shall be referred to as Mandatory Training.
3. Every [Investigator](#) shall complete Mandatory Training at least every four years and, additionally, any time
 - a. JWU revises its [FCOI](#) Policy in any manner that affects the requirements to which the [Investigator](#) is subject;
 - b. an [Investigator](#) is new to JWU; or
 - c. JWU finds that an [Investigator](#) is not in compliance with JWU's [FCOI](#) Policy or [Management Plan](#) (discussed below).

Disclosure of Significant Financial Interests

4. A [Disclosure of Significant Financial Interests](#) ("[Disclosure](#)") shall include all [Significant Financial Interests](#) of the [Investigator](#) (and also those of the [Investigator's](#) spouse, domestic partner, and/or dependent children) that:
 - a. reasonably appear to be related to the [Investigator's Institutional Responsibilities](#); or
 - b. involve any reimbursed or sponsored travel related to the [Investigator's Institutional Responsibilities](#) (including at minimum the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration).
5. Each [Investigator](#) must submit a [Disclosure](#) using [JWU's Disclosure of Significant Financial Interests form\(s\)](#) as follows:
 - a. Prior to submitting an application for federally sponsored [Research](#)
 - b. Within 30 days of acquiring (e.g., through purchase, marriage, or inheritance) or discovering a new [Significant Financial Interest](#)
 - c. At least annually, in accordance with the specific time period prescribed by JWU (within one week

before the anniversary of the original official award). Such annual disclosure shall include

- i. any information that was not disclosed initially to JWU (with an explanation as to why it was not previously disclosed); and
- ii. updated information regarding any previously disclosed [Significant Financial Interest](#) (e.g., the updated value of a previously disclosed equity interest).

Review and Monitoring Process

6. In keeping with [42 C.F.R. § 50.604\(d\)](#), JWU has designated as its [Institutional Official](#) its provost (or the provost's designee) to solicit and to review [Disclosures](#) from each [Investigator](#) who is planning to participate in, or is participating in, federally sponsored [Research](#). The [Institutional Official](#) may enlist the assistance of other university personnel as appropriate.
7. JWU has established a committee to review [FCOIs](#) ("FCOI Review Committee") and to assist the [Institutional Official](#) as appropriate at any time in the Review and Monitoring Process. The FCOI Review Committee shall include the provost, the chief financial officer, and the general counsel.
8. Promptly after submission of a [Disclosure](#), the [Institutional Official](#) shall confirm that a [Significant Financial Interest](#) exists and, if so, whether an [FCOI](#) exists. An [FCOI](#) will exist when the [Institutional Official](#) determines that a [Significant Financial Interest](#) could directly and significantly affect the design, conduct, or reporting of federally sponsored [Research](#).
9. If the [Institutional Official](#) determines that an [FCOI](#) exists, the [Institutional Official](#) shall determine whether the [FCOI](#) can be managed and, if so, shall develop (or require the [Investigator](#) to develop) and implement a written [Management Plan](#) within the meaning of [42 C.F.R. § 50.604\(g\)](#). The [Institutional Official](#) may require the [Investigator](#) to supplement the [Disclosure](#) with additional information as reasonably necessary.
10. Before any federally sponsored [Research](#) goes forward, the affected [Investigator](#) must agree to and sign the [Management Plan](#), and the FCOI Review Committee must, by a majority vote, approve the [Management Plan](#).
11. A [Management Plan](#) shall include, at minimum, one or more of the following steps in keeping with [FCOI](#) regulations and the nature of the [FCOI](#):
 - a. Public disclosure of the [FCOI](#) (e.g., when presenting or publishing the [Research](#))
 - b. For [Research](#) involving human subjects, disclosure of the [FCOI](#) directly to the subjects
 - c. Appointment of an independent monitor
 - d. Modification of the plan of [Research](#)
 - e. Change of personnel or personnel responsibilities or disqualification of the affected [Investigator](#) from participation in all or a portion of the [Research](#)
 - f. Reduction or elimination of the [Significant Financial Interest](#) (e.g., sale of the relevant equity interest)
 - g. Severance of relationships that create the [FCOI](#)
 - h. A plan for ongoing monitoring of the [Investigator](#)
12. For awards issued by the National Science Foundation (NSF), and in accordance with [Chapter IX.A. of the NSF's Proposal & Award Policies & Procedures Guide](#), if the reviewer(s) determine(s) that imposing 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 reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

13. The [Institutional Official](#) shall monitor compliance with the [Management Plan](#) and shall collaborate with the FCOI Review Committee to determine and impose remedies for noncompliance, which might include (among other remedies) suspending or terminating the [Research](#).
14. If at any time the [Institutional Official](#) or any member of the FCOI Review Committee discovers that an [Investigator](#) failed appropriately to disclose a [Significant Financial Interest](#), the [Investigator](#) will be required to complete, sign, and submit a [Disclosure](#). Assessment of the [Disclosure](#) will proceed in the manner outlined above.
15. If at any time the [Institutional Official](#) or any member of the FCOI Review Committee discovers that an [FCOI](#) was not disclosed or managed appropriately, the FCOI Review Committee will, within 120 days of discovery, complete a retrospective review of the affected [Investigator's](#) activities to determine whether any of the [Research](#) was biased in design, conduct, or reporting. The [Institutional Official](#) and the FCOI Review Committee may request additional information from the affected [Investigator](#) as reasonably necessary. The retrospective review will include the following at minimum:
 - a. Project number, if any, assigned by the [Institutional Review Board](#)
 - b. Project title
 - c. Name and contact information for [Principal Investigator](#)
 - d. Name of the affected [Investigator](#) (if different from the [Principal Investigator](#))
 - e. Name of the entity with which the [Investigator](#) has an [FCOI](#)
 - f. Reason(s) for the retrospective review
 - g. Detailed methodology used for the retrospective review
 - h. Findings of the retrospective review
 - i. Conclusions of the retrospective review
16. Based on the outcome of the retrospective review, the [Institutional Official](#) may develop or implement a [Management Plan](#) (if one does not exist) or modify the [Management Plan](#) (if one exists); take steps to mitigate bias; and take other steps, which might include (among other things) the following:
 - a. Require the [Investigator](#) to complete additional training
 - b. Undertake additional audits or monitoring
 - c. Require that subjects be notified and/or be asked to sign updated consent forms
 - d. Impose sanctions or require additional remedies to be determined based on the circumstances
 - e. Suspend or terminate the [Research](#)

In the case of clinical [Research](#) related to a drug, medical device, or treatment, the [Investigator](#) must disclose the [FCOI](#) in all public presentations of the [Research](#) results and request that previous publications be amended to include the disclosure.

Subrecipients

17. JWU shall ensure all subrecipients' compliance with the [FCOI regulations](#) by entering into a written agreement with each subrecipient specifying whether JWU's [FCOI](#) policy or the applicable policy of the subrecipient shall apply to subrecipient [Investigators](#). Among other things, the agreement shall specify when subrecipients shall report [FCOIs](#) to JWU, such that JWU may satisfy its reporting requirements.

Reporting to [Sponsor\(s\)](#)

18. Should any [FCOI](#) or noncompliance require reporting to a federal sponsor, the Institutional Official shall report it in accordance with the [FCOI regulations](#). If the funding for the [Research](#) is a subaward from a prime federal sponsorship awardee, reports shall be made to the prime awardee such that the prime awardee may

fulfill its reporting obligations to the federal sponsor prior to the expenditure of any federal funds and within 60 days of any subsequently identified [FCOI](#).

19. For awards issued by NSF, and in accordance with [Chapter IX.A. of the NSF's Proposal & Award Policies & Procedures Guide](#), JWU will notify NSF's Office of the General Counsel if JWU finds that it is unable to satisfactorily manage a conflict of interest and if JWU finds that research will proceed without the imposition of conditions or restrictions because imposing them would be either ineffective or inequitable, and 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.
20. If JWU identifies an [FCOI](#) and eliminates it prior to the expenditure of any [federal](#) funds, JWU will not be required to submit an [FCOI report](#) to the applicable [federal](#) agency.

Public Accessibility

21. Prior to the expenditure of federal funds, JWU will ensure public accessibility of information, via response to a requestor within five business days of the request, about any [Significant Financial Interest](#) that meets the following criteria:
 - a. The [Significant Financial Interest](#) was disclosed and is still held by the [Investigator](#);
 - b. A determination has been made that the [Significant Financial Interest](#) is related to the federally - funded [Research](#); and
 - c. A determination has been made that the [Significant Financial Interest](#) is an [FCOI](#).

The information to be made available shall be consistent with the requirements of [PHS](#) regulations.

Confidentiality

22. To the extent permitted by law, all [Disclosures](#), [Management Plans](#), and related information will be confidential. However, JWU may make such information available to the agency funding an [Investigator's Research](#) or to a requestor of information concerning an [FCOI](#) related to federal funding or to the primary entity that made the funding available JWU, if requested or required.

Record Retention

The [Institutional Official](#) will retain all disclosure forms, conflict management plans, and related documents for a period of at least three years from the date the final expenditure report is submitted to the federal agency or to the prime awardee or such longer period as JWU policy or applicable law may require.

Related Documents:

- Conflict of Interest and Commitment Policy
- Policy on Pursuit and Administration of Grants and Cooperative Agreements
- Disclosure of Significant Financial Interests (SFIs) form

Policy Contact(s):

- Policy issues or concerns should be directed to the provost or the provost's designee.
- Grant compliance issues should be directed to the director of grants & sponsored program administration.

Originally Issued: July 8, 2019

Policy Owner: Provost



Disclosure of Significant Financial Interests (SFIs)

Investigator information:

Name _____ Campus _____
 E-mail address _____ College _____
 Preferred phone # _____ Department _____
 Role in the project Principal Investigator Project Director Other Senior/Key Personnel
 Employer (if not JWU) _____

Project information:

Title _____
 Beginning date Click or tap to enter a date. Ending date Click or tap to enter a date.
 Sponsor (if any) _____

Type of Disclosure: Choose an item.

Most recent date financial conflict of interest (“FCOI”) training was completed: Click or tap to enter a date.

Disclosures:

Please respond to the questions below to disclose SFIs as defined in [42 C.F.R. §50.603](#) that may reasonably appear to relate to your Institutional Responsibilities, also as defined in [42 C.F.R. §50.603](#).

Publicly Traded Entity

- Have you, your spouse/domestic partner, or your dependent child received any income or payment for services from any publicly traded entity in the past 12 months that exceeds \$5,000 in the aggregate and that may reasonably appear to relate to your Institutional Responsibilities? Yes No
- Do you, your spouse/domestic partner, or your dependent child own stock, stock options, or any other ownership interest in any publicly traded entity that exceeds \$5,000 in value in the aggregate and that may reasonably appear to relate to your Institutional Responsibilities? (Equity interest does not include interests in mutual funds and retirement funds in which you do not directly control investment decisions.) Yes No

Non-Publicly Traded Entity

- Have you, your spouse/domestic partner, or your dependent child received any income or payment for services from any non-publicly traded entity in the past 12 months that exceeds \$5,000 in the aggregate and that may reasonably appear to relate to your Institutional Responsibilities? Yes No
- Do you, your spouse/domestic partner, or your dependent child own stock, stock options, or any other ownership interest in any non-publicly traded entity that exceeds \$5,000 in the aggregate and that may reasonably appear to relate to your Institutional Responsibilities? Yes No

Intellectual Property

- Have you, your spouse/domestic partner, or your dependent child received any payments in the past 12 months for any intellectual property rights or interests (e.g., patents, copyrights assigned or licensed to a party other than JWU) exceeding \$5,000 and that may reasonably appear to relate to your Institutional Responsibilities? Yes No

Travel

- Have you, your spouse/domestic partner or your dependent child received any travel reimbursement or been sponsored for travel (i.e., travel expenses paid and not reimbursed so that the exact monetary value may not be readily available) within the last 12 months when such travel related to your Institutional Responsibilities? (This does not include travel sponsored or reimbursed by a federal, state, or local government agency, a U.S. institution of higher education or an affiliated research institute, an academic teaching hospital, or a medical center.) Yes No

If you answered “Yes” to any of the questions above, please complete Part B of this form.

INVESTIGATOR CERTIFICATION:

- I have read, understand, and will comply with JWU’s Conflict of Interest and Commitment Policy and Financial Conflict of Interest Policy.
- The information provided above and in any attachments hereto (a) reflects any and all of my SFIs related to my Institutional Responsibilities and (b) truthfully, completely, and accurately reflects my SFIs to the best of my knowledge.
- I agree to comply with any conditions or restrictions imposed by JWU for the purpose of managing, reducing, or eliminating actual or potential conflicts of interest in connection with this grant. If I am unable to comply, I understand that JWU may decline the grant or terminate the PHS-funded Research.

Signature Date

Name (please print)

PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR CERTIFICATION:

The following people (or roles) meet the definition of Investigator for the above project, and I certify that they all will comply with the disclosure requirements of the JWU Financial Conflict of Interest Policy:

Signature Date

Name (please print)

IF “YES” TO ANY OF THE QUESTIONS ABOVE, INSTITUTIONAL OFFICIAL CERTIFICATION:

- _____ No Financial Conflict of Interest appears to exist.
- _____ A Financial Conflict of Interest may exist. No Research may go forward until the requisite Management Plan is in place, and the sponsor has been notified.

Signature Date

Name (please print)



Disclosure of Significant Financial Interests

Please complete this page for each entity in which you have a Significant Financial Interest (“SFI”). Use a different page for each person (i.e., you, your spouse/domestic partner, or dependent child) who has an SFI. For further guidance, please see JWU’s Financial Conflict of Interest Policy and [42 C.F.R. Part 50, Subpart F](#).

Investigator information:

Name	_____	Campus	_____
E-mail address	_____	College	_____
Preferred phone #	_____	Department	_____

Information of person with SFI (if different from above):

Name	_____	Campus	_____
Email address	_____	College	_____
Preferred phone #	_____	Department	_____

Entity in which the Investigator (or Investigator’s spouse/domestic partner or dependent child) has an SFI:

Name _____

Address _____

Website _____

Form of compensation

- | | |
|---|---|
| <input type="checkbox"/> Salary | <input type="checkbox"/> Fees (e.g., honoraria, consulting, authorship, etc.) |
| <input type="checkbox"/> Stock, stock option, or other ownership interest | <input type="checkbox"/> Intellectual property interest |
| <input type="checkbox"/> Other: _____ | |

Approximate value of compensation _____

Description of compensation _____

Description of relationship to the entity and/or work performed for it _____

Relationship of work to Institutional Responsibilities, including Research _____

- Sponsored travel

Purpose _____

Destination _____

Duration of trip _____

Approximate value (if known) _____