



Financial Conflict of Interest in Research Policy and Procedures

I. Scope and Application

These Financial Conflict of Interest in Research Policy and Procedures (“Policy”) apply to all Johnson & Wales University (“JWU”) employees (including student employees acting in their capacity as such), agents, officers, and persons directly under university control or acting on the university’s behalf (collectively, “Covered Persons”).

II. Policy

- A. Covered Persons must 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. This Policy, which is based on federal regulations published at 42 C.F.R. § Part 50, Subpart F, is 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”).
- B. 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 this Policy.

III. Procedures

A. General

- 1. Terms and Authority
 - a) With the exception of terms defined in this Policy, capitalized terms are defined in 42 C.F.R. § 50.603 and elsewhere in the Public Health Services (“PHS”) FCOI regulations. However, if a particular Sponsor applies different definitions, then those definitions will control as the context requires.
 - b) 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 this Policy, then the more restrictive requirements must be followed unless otherwise required by law, university policy, or specific award provisions.
- 2. Investigator Responsibilities
 - a) Learning/Training
 - (1) Prior to seeking or engaging in any federally sponsored Research, every Investigator must review and become familiar with this Policy and the 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”), referred to as “Mandatory Training”:
 - (a) Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (ID 15070); and
 - (b) Institutional Responsibilities as They Affect Investigators (ID 15072).
 - (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 [[42 C.F.R. § 50.604\(b\)\(1\)](#)];
 - (b) an Investigator is new to JWU [[42 C.F.R. § 50.604\(b\)\(2\)](#)]; or
 - (c) JWU finds that an Investigator is not in compliance with JWU’s FCOI Policy or Management Plan (discussed below) [[42 C.F.R. § 50.604\(b\)\(3\)](#)].
- b) Disclosure of Significant Financial Interests
 - (1) 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).
 - (2) 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).
- B. Review and Monitoring Process
 1. 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.

2. JWU has established a committee (“FCOI Review Committee”) to review FCOIs 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.
3. JWU shall complete the following steps within 60 days of the Investigator’s Disclosure [[42 C.F.R. § 50.605\(a\)\(2\)](#)]:
 - a) 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.
 - b) 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) and 42 C.F.R. § 50.605(a). The Institutional Official may require the Investigator to supplement the Disclosure with additional information as reasonably necessary.
 - c) Depending on the nature of the Significant Financial Interest, JWU may determine that additional interim measures are necessary with regard to the Investigator’s participation in the federally sponsored Research project between the date of disclosure and the completion of JWU’s review.
4. 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.
5. 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) [[42 C.F.R. § 50.605\(a\)\(1\)\(i\)](#)];
 - b) For Research involving human subjects, disclosure of the FCOI directly to the subjects and to the applicable Institutional Review Board (“IRB”) [[42 C.F.R. § 50.605\(a\)\(1\)\(ii\)](#)];
 - c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest [[42 C.F.R. § 50.605\(a\)\(1\)\(iii\)](#)];
 - d) Modification of the Research plan [[42 C.F.R. § 50.605\(a\)\(1\)\(iv\)](#)];
 - e) Change of personnel or personnel responsibilities or disqualification of the affected Investigator from participation in all or a portion of the Research [[42 C.F.R. § 50.605\(a\)\(1\)\(v\)](#)];
 - f) Reduction or elimination of the Significant Financial Interest (e.g., sale of the relevant equity interest) [[42 C.F.R. § 50.605\(a\)\(1\)\(vi\)](#)];
 - g) Severance of relationships that create the FCOI [[42 C.F.R. § 50.605\(a\)\(1\)\(vii\)](#)]; or
 - h) A plan for ongoing monitoring of the Investigator [[42 C.F.R. § 50.605\(a\)\(4\)](#)].
6. 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.

7. 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.
8. 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.
9. 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; and
 - h) Findings of the retrospective review.
10. Conclusions of the retrospective review.
 - a) 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:
 - (1) Require the Investigator to complete additional training;
 - (2) Undertake additional audits or monitoring;
 - (3) Require that subjects be notified and/or be asked to sign updated consent forms;
 - (4) Impose sanctions or require additional remedies to be determined based on the circumstances; or
 - (5) Suspend or terminate the Research.
 - b) 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.

C. Subrecipients

1. 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.

D. Reporting to Sponsor(s)

1. 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.
2. 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.
3. 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.

E. Public Accessibility

1. 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 [[42 C.F.R. § 50.605\(a\)\(5\)\(i\)\(A\)](#)];
 - b) JWU determines that the Significant Financial Interest is related to the funded research [[42 C.F.R. § 50.605\(a\)\(5\)\(i\)\(B\)](#)]; and
 - c) JWU determines that the Significant Financial Interest is an FCOI [[42 C.F.R. § 50.605\(a\)\(5\)\(i\)\(C\)](#)].

F. Confidentiality

1. 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.

G. Record Retention

1. 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.

IV. **Policy Owner**

Provost

V. **Effective Date**

Originally issued: July 2019

Last update: July 2025



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	_____	Ending date	_____
Sponsor (if any)	_____		

Type of Disclosure: _____

Most recent date financial conflict of interest (“FCOI”) training was completed: _____

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

Yes No

- Have you, your spouse/domestic partner, or your dependent child received any income or payment for services from any publicly traded entity within the past 12 months that exceeds \$5,000 in the aggregate and that may reasonably appear to relate to your Institutional Responsibilities?
- 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 or that represents more than a 5 percent ownership interest in such an entity 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.)

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 within the past 12 months that exceeds \$5,000 in the aggregate and that may reasonably appear to relate to your Institutional Responsibilities?
- 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 or that represents more than a 5 percent ownership interest in such an entity and that may reasonably appear to relate to your Institutional Responsibilities?

Foreign Financial Interests

- Have you, your spouse/domestic partner, or your dependent child received any income or payment within the past 12 months from any foreign entity, including, without limitation, foreign institutions of higher education and foreign local, provincial, or other governments, for seminars, lectures, or teaching engagements; service on advisory committees or review panels; reimbursed or sponsored travel (i.e., travel expenses paid and not reimbursed so that the exact monetary value may not be readily available); or other services or costs, that exceed \$5,000 in the aggregate?

Intellectual Property

- Have you, your spouse/domestic partner, or your dependent child received any payments within 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?

Travel

- Have you, your spouse/domestic partner or your dependent child received any travel reimbursement or been sponsored for travel within the last 12 months when such travel related to your Institutional Responsibilities? (This does not include domestic 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.)

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

Salary	Fees (e.g., honoraria, consulting, authorship, etc.)
Stock, stock option, or other ownership interest	Intellectual property interest
Other:	_____

Approximate value of compensation	_____
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Description of compensation	_____
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Description of relationship to the entity and/or work performed for it	_____
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Relationship of work to Institutional Responsibilities, including Research	_____
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Sponsored travel

Purpose	_____
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Destination	_____
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Duration of trip	_____
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Approximate value (if known)	_____
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