

NCA Self Study
Criterion 2 Documents

Eastern Illinois University

Year 2014

Financial Conflict of Interest Policy

NCA Self-Study Committee

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Eastern Illinois University

Policy on Financial Conflict of Interest

for NSF-funded Projects

Much of this document was drawn directly from material published by the National Institutes of Health and the National Science Foundation. Some material on Form A was copied or modified from a similar form published by the University of Oregon. Eastern Illinois University thanks the University of Oregon for permission to use this wording. Eastern also thanks Indiana State University for permission to use a sentence from their FCOI policy.

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I. Introduction

Eastern Illinois University recognizes the importance of promoting objectivity in research for which National Science Foundation (NSF) funding is sought or accepted. In the design, conduct, and reporting of such research, the university intends to avoid bias caused by financial conflicts of interest on the part of the investigator. This document elaborates Eastern's policy on Financial Conflict of Interest.

II. Relevant Regulations

Eastern's policy is designed to comply with all regulations of NSF. Specifically, Eastern acknowledges the Award and Administration Guide, Chapter IV, Section A: "Conflict of Interest Policies"

III. Applicability

This policy applies to any EIU investigator who participates in the design, conduct or reporting of research or educational activities funded or proposed for funding by NSF. The policy also applies to subawardees, as described in section V.

IV. Definitions

A. Investigator:

The term "investigator" means the principal investigator, co-principal investigators/co-project directors, and any other person at EIU who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

B. Significant Financial Interest (SFI)

The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term "significant financial interest" does not include:

1. salary, royalties or other remuneration from the applicant institution;
2. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
3. income from service on advisory committees or review panels for public or nonprofit entities;
4. an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
5. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve-month period.

The foregoing five exclusions are the only ones that EIU recognizes as valid.

C. Financial Conflict of Interest (FCOI)

A significant financial interest rises to the level of a FCOI if the Institutional Official concludes that the significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

Eastern Illinois University, rather than the investigator, makes the determination of whether a SFI should be considered a FCOI.

V. Subrecipients

If Eastern carries out research through a subrecipient (e.g., a subcontractor or a consortium member), Eastern is responsible for ensuring that each subrecipient Investigator complies with NSF FCOI regulations. In consultation with the subrecipient, Eastern will craft a written agreement that ensures such compliance by either of the following two options:

(1) Depend on the Subrecipient's FCOI policy

If the parties agree that the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of a written agreement with Eastern that the subrecipient's policy complies with NSF policy. Additionally, the written agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Eastern Illinois University.

By the time of the initial application for funding from the NSF, the potential subawardee shall supply Eastern with a copy the disclosure of financial interests submitted by each investigator from the subawardee institution.

(2) Depend on Eastern's FCOI Policy

If the subrecipient is unable or unwilling to certify that its FCOI policy complies with NSF policy—or if Eastern prefers to depend on its own FCOI policy--then the written agreement between the two parties shall state that the subrecipient's Investigators must comply with Eastern's FCOI policy. The agreement shall also specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Eastern Illinois University. Such time period(s) shall be sufficient to enable Eastern to complete its review, management, and reporting obligations prior to the expenditure of any funds by the subrecipient and within 60 days of any subsequently identified FCOI.

The procedure for implementing this policy shall consist of adding an attachment to Eastern's standard form (based on the Federal Demonstration Project model agreement) for formalizing subawards.

VI. Institutional Official

Eastern Illinois University designates the Dean of the Graduate School as the Institutional Official responsible for FCOI compliance. The Institutional Official shall solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NSF-funded research. The Dean of the Graduate School may delegate any or all of these responsibilities by writing a letter that documents the delegation.

VII. Disclosures Required of Investigators

A. Initial Disclosure

Each Investigator who is planning to participate in research described in a grant application submitted to the NSF must disclose his or her financial interests (and those of the Investigator’s spouse and dependent children) no later than the time of application for NSF funded research. **Form A** shall be used for this disclosure.

B. Annual Disclosure

Each Investigator who is participating in research funded by NSF must submit an updated disclosure of financial interests to Eastern’s Institutional Official at least annually during the period of the award. Such disclosure shall include any information that was not included in the Initial Disclosure or in a subsequent disclosure of financial interests (e.g., any financial conflict of interest identified on a NSF-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed financial interest (e.g., the updated value of a previously disclosed equity interest). **Form A** shall be used for this disclosure.

Annual disclosures are due by June 30 of each year.

C. Disclosure of New Financial Interest(s)

Each Investigator who is participating in research funded by NSF must submit an updated disclosure of financial interests to Eastern’s Institutional Official within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest. **Form A** shall be used for this disclosure.

D. Retrospective Disclosure

If Eastern determines that an investigator (who may be a subrecipient) failed to deliver timely disclosure of a financial interest, the investigator shall be required to submit a Retrospective Disclosure. **Form A** shall be used for this disclosure.

VIII. Guidelines for Analyzing Financial Interests

A. Identifying SFI’s

Upon receipt of Form A – Part 2 the Institutional Official shall use the following decision rule: A financial interest rises to the level of a FCOI if the financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities. **Form B** shall be used to document this analysis.

B. Timing of Analysis by the Institutional Official

Type of Disclosure	Required Completion Date of Analysis
Initial	Prior to expenditure of funds
Annual	Within 60 days of disclosure
New Financial Interest	Within 60 days of disclosure
Retrospective	Within 60 days of discovery of noncompliance

IX. Management of Financial Conflicts of Interest

Once a FCOI has been identified and documented, Eastern Illinois University shall be responsible for developing and implementing a management plan that shall specify the actions that have been, and shall be taken to manage such financial conflict of interest. The Institutional Official shall develop this management plan in consultation with the investigator. **Form C** shall be used to document the management plan.

A management plan shall include the following key elements:

- (1) Role and principal duties of the conflicted Investigator in the research project;
- (2) Conditions of the management plan (vida infra);
- (3) How the management plan is designed to safeguard objectivity in the research project;
- (4) Confirmation of the Investigator's agreement to the management plan;
- (5) How the management plan will be monitored to ensure Investigator compliance; and
- (6) Other information as needed.

Conditions specified by the plan may include any or all of three options: manage, reduce, or eliminate the FCOI. Examples of each type of action include, but are not limited to the following:

Manage

Public disclosure of financial conflicts of interest:

- in publications and/or presentations in which the research results are circulated,
- to other staff working on the project,
- to human research subjects participating in the research (this information is usually provided in consent forms), and/or
- to the grantee institutions' Institutional Review Boards (these boards ensure the rights and safety of people participating in clinical trials).

Ensure that protections are in place to prevent the exertion of inappropriate pressure on other staff working on the grant-funded project:

- ensuring that staff who work on the grant knew where to bring any concerns about the impact of the conflict on them or the research,
- ensuring that students and trainees were not involved with the company with which the researcher had a relationship, and/or
- gaining prior approval before allowing students and trainees to conduct research related to the company.

Other common methods to manage conflicts include:

- requiring researchers to notify the grantee institution when and how relationships with the outside companies changed (this included changes in equity amounts, changes in the nature of the researchers' relationship with the outside companies, changes in any funding of the research provided by the outside companies, and accrual of royalties),
- requiring researchers to ensure that an open exchange of research results would take place,
- monitoring or oversight of the grant research by grantee institution staff not related to the grant research, and
- limiting or prohibiting researchers from research involving human subjects.

Reduce

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

Modification of the research plan

Change of personnel or personnel responsibilities, or disqualification of personnel from participating in all or a portion of the research.

Reduction of the financial interest (e.g., by sale of equity interest)

Eliminate

Divestiture of the entire financial interest (e.g., by sale of equity interest)

Severance of relationships that create financial conflicts

Eastern shall monitor the Investigator's compliance with the management plan on an ongoing basis until the completion of the NSF-funded project. **Form D** shall be used to document the monitoring of the management plan.

If the Institutional Official determines 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 Institutional Official may allow the research to go forward without imposing such conditions or restrictions.

A decision by the Institutional Official may be appealed to the Provost within 30 days of the date of notification of the Institutional Official's decision.

X. Handling Noncompliance

Noncompliance with FCOI policy includes (but is not limited to) several possibilities: (1) failure by the Investigator to disclose a significant financial interest that is determined by Eastern to constitute a financial conflict of interest; (2) failure by the Investigator to comply with Eastern's FCOI policy or with a FCOI management plan; or (3) bias is found in the design, conduct, or reporting of NSF-funded research even if such bias was created with a management plan in place.

In the event that Eastern receives evidence of noncompliance with the university's FCOI policy or with an FCOI management plan, Eastern shall undertake the following action: Within 14 days of receipt of the evidence, the Institutional Official shall review the evidence and draw a conclusion as to whether noncompliance, in fact, occurred. The Institutional Official shall determine whether the noncompliance resulted in bias in the design, conduct, or reporting of the NSF-funded research. The Institutional Official shall also inform the Provost of possible noncompliance with Eastern's internal governing policy that covers financial conflict of interest.

If, as a result of the forgoing review, the Institutional Official concludes that Eastern is unable to satisfactorily manage a conflict of interest, the Institutional Official shall inform NSF's Office of Inspector General if Eastern within 14 days.

XI. Maintenance of Records

Eastern shall maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

XII. Enforcement mechanisms and sanctions

Eastern's FCOI policy is formalized with an internal governing policy. Enforcement mechanisms and sanctions will be determined by the process that is used whenever a violation of an internal governing policy has occurred.

XIII. Policy Changes

The institutional official may change this policy document, provided the change is documented with a memo to the Provost and the Director of Research and Sponsored Programs.

Form A – Part 1

Confidential
Eastern Illinois University
Financial Conflict of Interest (FCOI) Disclosure Form*

1. Investigator Name: _____
Status: Faculty Student Staff Other—specify: _____
Mailing address: _____
Phone: _____ E-mail: _____
Department or Unit _____

2. NSF Project Title: _____

3. Check one box to indicate the type of disclosure you are making:
 Initial Annual New Financial Interest Retrospective

4. Disclosure of Financial Interests
A. In making this disclosure, do not include any of the following items:
1. Salary, royalties or other remuneration paid by EIU to the investigator
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
3. Income from service on advisory committees or review panels for public or nonprofit entities.
4. Equity interest that, when aggregated for the investigator and the investigator’s spouse and dependent children, meets both of the following tests:
 • Does not exceed \$10,000 in value as determined by reference to public prices or other reasonable measures of fair market value at the time this form is submitted.
 • Does not represent more than 5% ownership interest in any single entity.
5. Salary, royalties, or other payments that, when aggregated for the investigator and the investigator’s spouse and dependent children are not expected to exceed \$10,000 during the twelve month period which begins on the date written in the response to Part 5.

B. Check all of the following that are expected to be true of you, your spouse, and/or any dependent children at any time during the 12 month period which begins on the date written in the response to Part 5.
 Salary or other payments for services (e.g., consulting fees or honoraria)
 Equity interest (e.g., stocks, stock options, or other equity interests)
 Intellectual property rights (e.g., patents and copyrights, and royalties from such rights)
 Anything else of monetary value that is not excluded in Part A

C. No Financial Interest
Check if none of the types of Financial Interest listed in Part B are anticipated to be true of you, your spouse, and/or any dependent children during the 12 month period which begins on the date written in the response to Part 5.

5. Investigator Assurance

I agree to abide by Eastern's Financial Conflict of Interest Policy. In submitting this form and any other required documents I certify that the information provided is true to the best of my knowledge. I supply this information for confidential review by Eastern Illinois University and for such other limited purposes as are required by law, regulation, or contract. I do not authorize release of it for any other purpose. I understand and agree that if there is a material change (an acquisition of a significant financial interest) to this information, I must submit a new disclosure and attachment within 30 days of that change.

Signature: _____ Date: _____

What should I do next?

If you checked only box 4. C., no further disclosure is required. Please mail this form in an envelope marked "Confidential" to the director of the Office of Research and Sponsored Programs.

If you checked any box in 4. B., then complete a separate Form A – Part 2 for each financial interest covered by the criteria in 4. B. Please mail both Form A – Part 1 and all copies of Form A – Part 2 in an envelope marked "Confidential" to the director of the Office of Research and Sponsored Programs.

What response can I expect?

If you checked only box 4. C., no response will be sent to you.

If you checked any box in 4. B., The director of the Office of Research and Sponsored Programs will review your information. The Dean of the Graduate School will review your information and, if necessary, contact you for discussion. If any of your financial interests meet the criteria for a Financial Conflict of Interest (FCOI), the Dean of the Graduate School will help you develop a management plan. You will receive written communication of all conclusions that result from review of your information.

*This form collects information which Eastern Illinois University must collect and analyze in order to qualify for funding from the National Science Foundation (NSF). This form includes some language taken directly from a form created by the University of Oregon.

Form A – Part 2

Confidential
Eastern Illinois University
Financial Conflict of Interest (FCOI) Disclosure Form*

1. Investigator Name: _____

2. NSF Project Title: _____

3. Check the type of financial interest that is disclosed in your response to Question 4B on Form A – Part 1.
(Check only one.)

- A. Salary or other payments for services (e.g., consulting fees or honoraria)
- B. Equity interest (e.g., stocks, stock options, or other equity interests)
- C. Intellectual property rights (e.g., patents and copyrights, and royalties from such rights)
- D. Anything else of monetary value that is not excluded in Part A

4. Name of the organization in which the financial interest exists:

5. Describe the type of business conducted by the organization:

6. The organization is:

- For profit (publicly-owned) For profit (privately-held) Non-profit
- Governmental

7. The financial relationship is between the organization and (Check all that apply.)

- Self Spouse Dependent Child(ren)

8. Estimated value of the financial interest: _____

9. In the box below, describe how the financial interest checked in Part 3 would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF.

I agree to abide by Eastern's Financial Conflict of Interest Policy. In submitting this form and any other required documents I certify that the information provided is true to the best of my knowledge. I supply this information for confidential review by Eastern Illinois University and for such other limited purposes as are required by law, regulation, or contract. I do not authorize release of it for any other purpose. I understand and agree that if there is a material change (an acquisition of a significant financial interest) to this information, I must submit a new disclosure and attachment within 30 days of that change.

Signature: _____ Date: _____

What response can I expect?

The Dean of the Graduate School will review your information and may contact you for discussion. If any of your financial interests meet the criteria for a Financial Conflict of Interest (FCOI), the Dean of the Graduate School will help you develop a management plan. You will receive written communication of all conclusions that result from review of your information.

*This form collects information which Eastern Illinois University must collect and analyze in order to qualify for funding from the National Science Foundation (NSF). This form includes some language taken directly from a form created by the University of Oregon.

Form C

**Eastern Illinois University
Financial Conflict of Interest Management Plan**

1. Investigator Name: _____
2. NSF Project Title: _____
3. Disclosed Financial Conflict of Interest: _____
4. Role and principal duties of the Investigator in the research project:

5. Conditions of the management plan include (check all that apply)

Reduce Manage Eliminate

6. List and describe all detailed actions that will be taken in order to accomplish the conditions of the management plan. Describe how each action will contribute to the objectivity of the research.

7. List and describe all detailed actions that will be taken in order to accomplish the conditions of the management plan. Describe how each action will contribute to the objectivity of the research.

8. List and describe all actions that will be taken in order to monitor this management plan. Include dates by which actions are to be accomplished.

9. Assurances:

We agree to the management plan as it is described on this form.

Signature: _____ Date: _____
Investigator

Signature: _____ Date: _____
Institutional Official

Form D

**Eastern Illinois University
Monitoring Report on
Financial Conflict of Interest Management Plan**

1. Investigator Name: _____
2. NSF Project Title: _____
3. Disclosed Financial Conflict of Interest: _____
4. List and describe all actions that were required by the financial management plan. Indicate whether the actions have been completed. Add explanations as necessary.

5. Conclusion: The management plan has has not been followed to date.

Signature: _____ Date: _____
Institutional Official