

University of Wisconsin Oshkosh
Office of Grants and Faculty Development

Financial Conflict of Interest in Federal Research	
Effective Date: August 24, 2012	Last Reviewed: August 22, 2012

Financial Conflict of Interest

1. PURPOSE:

Consistent with federal regulations (42 CFR Part 50, 45 CFR Part 94), the financial conflict of interest regulations were established to promote objectivity in research for which Public Health Service (PHS) funding is sought and to promote responsible prospective contractors. The regulations establish standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under federal grants or cooperative agreements will be free from bias resulting from Investigator financial conflict of interest. The University of Wisconsin Oshkosh is committed to ensuring the public's trust that Federally-supported research is conducted with the highest scientific and ethical standards.

This financial conflict of interest policy applies to all Investigators of the University of Wisconsin Oshkosh that have research funded under federal grants or cooperative agreements and applicants seeking federal funding. This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and explains the process for notifying the Institution if a conflict would arise.

The Institutional Official (Provost/Vice Chancellor) is responsible for ensuring implementation of this policy administered by the Office of Grants and Faculty Development.

2. DEFINITIONS:

UW Oshkosh has adopted the following PHS regulatory (42 CFR Part 50) definitions:

Institution: any domestic or foreign, public or private, entity or organization that applies for or that receives federal funding by means of a grant or cooperative agreement

Research: any systematic investigation, study, or experiment designed to contribute to generalizable knowledge

Investigator: the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a research project that is federally funded or proposed for such funding (e.g., graduate students, postdoctoral associates, senior scientists, collaborators, or consultants)

Subrecipient Investigator: any individual that will perform a portion of the scope of work or objectives of the project (e.g. subgrantee, subcontractor, or collaborator) whose primary affiliation is with an entity other than the lead Institution.

Institutional Official: the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests related to the Investigator's institutional responsibilities.

Financial Interest: anything of monetary value received or held by an Investigator or an Investigator's immediate family (spouse and dependent children), whether or not the value is readily ascertainable, including, but not limited to:

- a. salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works)
- b. any equity interests (e.g., stocks, stock options, or other ownership interests)
- c. Intellectual property right and interest (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Significant Financial Interest (SFI): a financial interest consisting of one or more of the following interests of the Investigator and his or her immediate family (spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional responsibilities:

- a. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value
- b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest)
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests not reimbursed through the Institution
- d. Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their

institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources. Excluded sources include: U.S. Federal, state, or local government agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest (SFI) Exclusions:

- a. Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution
- b. Income from authorship of academic or scholarly works
- c. Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights
- d. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization
- e. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles
- f. Income from seminars, lectures, or teaching engagements 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
- g. Income from service on advisory committees or review panels for a federal, state, or local government agency, Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Financial Conflict of Interest (FCOI): a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the federally-funded research

Investigator's Institutional Responsibilities: an Investigator's professional responsibilities on behalf of the institution, which may include activities in teaching, research or research consultation, professional practice, institutional committee/board memberships

Manage: taking action to address a financial conflict of interest (FCOI), which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias.

3. PROCEDURE FOR DISCLOSURE:

When submitting an application to the Office of Grants and Faculty Development for federal grant or cooperative agreements, any individual meeting the federal definition of Investigator

(as defined above) and their immediate family members must disclose any Significant Financial Interests (SFIs). SFIs include financial interests that are related to an Investigator's institutional responsibilities.

Financial Disclosure Form:

A Financial Disclosure Form (Appendix A) is used to disclose Significant Financial Interests and must be filled out when applying for federal grants or cooperative agreements, annually, and on an ad hoc basis as described below:

- a. Application Disclosure: At the time of submission of application materials for federal grants or contracts, a Financial Disclosure Form must be attached to the Internal Review Form.
- b. Annual Disclosures: Investigators with federal funding must update their Financial Disclosure Form on an annual basis. The submittal of the annual disclosure will coincide with the due date of the project's Progress Report.
- c. Ad hoc Disclosures: In addition to annual disclosure, certain situations require ad hoc disclosure. All investigators, to whom this policy applies, must submit to the Institution an ad hoc disclosure within 30 days of discovering or acquiring any new or additional Significant Financial Interest.

Treatment of Subcontractors, Subrecipients, and Collaborators:

When UW Oshkosh carries out a federally-funded grant or cooperative agreement through subcontractors, subrecipients or collaborators, UW Oshkosh must take reasonable steps to ensure that the subrecipient investigator is in compliance with federal regulations relating to financial conflicts of interest. UW Oshkosh fulfills this requirement by setting forth the obligations of each party with respect to conflict of interest management and reporting in the agreement between the parties.

4. PROCEDURE FOR EVALUATION:

Evaluation of the Financial Disclosure Forms

The Financial Disclosure Forms are reviewed by the Institutional Official or their designee, who determines whether a potential conflict of interest exists. If a potential financial conflict of interest is determined, the Institutional Official will appoint an ad hoc Research Responsibility Committee to review the case and decide if the conflict is manageable. Membership of the ad hoc Research Responsibility Committee will consist of the following expertise: (1) IRB member, (1) IACUC member, (1) Faculty member from discloser's department, and (1) Faculty member that has no connection to the research proposed.

a. No Financial Conflict of Interest:

1. No further action is needed

2. The proposal is submitted to the federal funding agency
3. Award is accepted
4. At the time of award acceptance, a meeting is set up with the Principal Investigator, Director of the Office of Grants and Faculty Development, and the Grant Accountant in charge of the award
5. An account is set up for the award

b. Financial Conflict of Interest Exists:

1. Proposal is submitted to the federal funding agency
2. The Research Responsibility Committee reviews Financial Disclosure Forms and determines if the conflict can be managed.

a. Conflict is manageable

1. FCOI Management Plan (Appendix B) is prepared to manage, reduce, or eliminate the conflict of interest. The Institutional Official must approve the FCOI Management plan and the Investigator must agree to the terms of the plan before any related research goes forward. For complex situations, the Research Responsibility Committee may periodically review the ongoing activity to ensure compliance with the management plan.
2. Award is accepted
3. Funding agency is notified (if required by the agency)
4. At the time of award acceptance, a start up meeting is scheduled with the Principal Investigator, Director of the Office of Grants and Faculty Development, and the Grant Accountant in charge of the award.
5. An account is established for the award once all COI cases are cleared by the Research Responsibility Committee

b. Conflict is unmanageable

1. Funding agency is notified (if required by the agency)
2. Award is not accepted

5. INSTITUTIONAL RESPONSIBILITIES:

- a. Take necessary actions to manage FCOIs of Investigators
- b. Develop management plans and monitor compliance
- c. If a SFI is identified that was not disclosed or reviewed in a timely manner, the Institutional Official or their designee shall review the SFI within sixty (60) days and determine if a FCOI exists. If a FCOI exists, the Institution must report it to the funding agency if required and implement an interim management plan if needed.
- d. In cases of non-compliance, the Institutional Official will follow reporting requirements in accordance with the funding agency. The Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate is implemented.
 1. If disciplinary action is taken, a written explanation by the Institutional Official will be described in a letter to the Investigator and the Research Responsibility Committee. The Institutional Official will notify the Investigator of the right to appeal the decision.
 2. The Research Responsibility Committee will complete a Retrospective Review (Appendix C) to determine if the research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the research.
 - a. If bias is determined during the Retrospective Review, the Institutional Official will create an action plan and update any reports as required by the funding agency. PHS agencies require submission of a Mitigation Report in eRA Commons FCOI Module if bias is found.

6. TRAINING:

Financial Conflict of Interest Training Requirements

- a. Each Investigator must complete training prior to engaging in research related to any federally funded grant. A training course in Conflicts of Interest is provided through CITI Program which includes a module with UW Oshkosh specific guidelines.
- b. A refresher training course through CITI Program must be completed at least every 4 years
- c. Training must occur immediately under the following circumstances:
 1. Institutional FCOI policies change in a manner that affects Investigator requirements
 2. An institution finds an Investigator noncompliant with Institution's FCOI policy or FCOI Management Plan

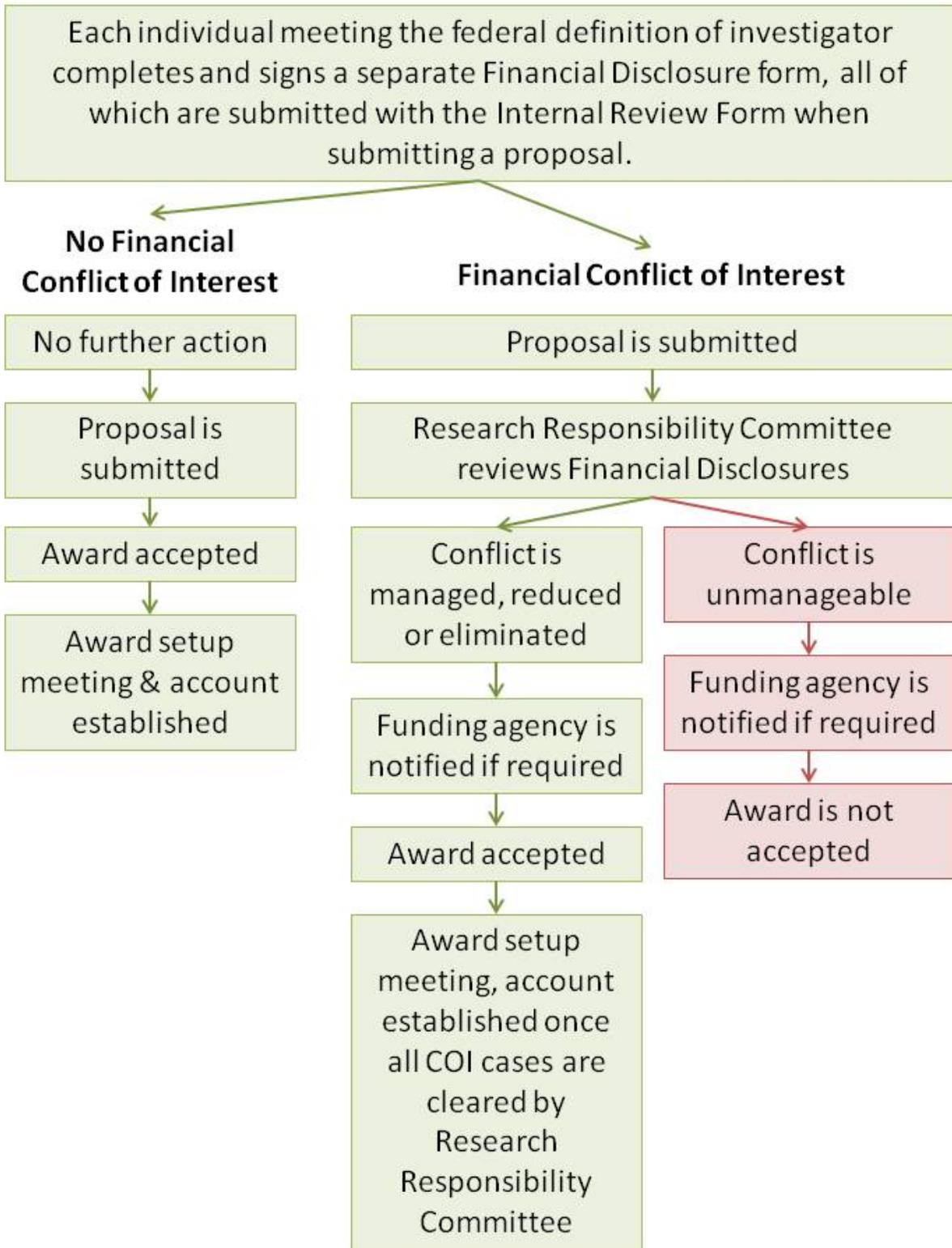
7. RECORD RETENTION:

The Institutional Official or their designee will retain all disclosure forms, conflict management plans, and related documents for a period of seven years from the date of the final closure report.

8. CONFIDENTIALITY:

To the extent permitted by the law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research of the faculty member or to a requestor within five business days of information concerning financial conflict of interest related to the funding. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of the disclosure.

Financial Conflict of Interest Process



Significant Financial Interest (SFI) Reference Chart

Remuneration and equity/ownership interests of the Investigator and/or the Investigator's immediate family as defined the table below:

Type of entity	Type of financial interest	Value
Publicly traded entity	Any remuneration, including but not limited to: <ul style="list-style-type: none">• Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship)	Totaling \$5,000 or more in the preceding twelve months alone or in aggregate with equity interests and/or reimbursed/sponsored travel in/from same entity
	Equity interests (e.g., stocks, stock options, convertible bonds, or other ownership interests)	Totaling \$5,000 or more (as determined through reference to public prices or other reasonable measures of fair market value) alone or in aggregate with other remuneration received from same entity
Non-publicly traded entity	Any remuneration, including but not limited to: <ul style="list-style-type: none">• Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship)	Totaling \$5,000 or more in the preceding twelve months
	Equity interests (e.g., stocks, stock options, convertible bonds, or other ownership interests)	Any amount
N/A	Intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights)	Any amount
Any entity that is <i>not</i> a federal, state, or local government agency; an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education	Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available)	Any amount

Appendix A: Financial Disclosure Form

(Submitted pursuant to the requirements of the UW Oshkosh Financial Conflict of Interest in Federal Research Policy)

Part I: Financial Interests

Investigator Name:	
Investigator Title:	
Department/Unit:	

I am reporting on activities: (Please check all that apply)

- At the time of submission of a grant application for federal funding
- Annual reporting requirement for the year: _____
- Ad hoc as an addendum to my most recent financial disclosure report

Yes No Please answer the following questions.

- 1. *Compensation (including travel expenses):* Have you or a member of your family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, and the like?
- 2. *Equity:* Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity?
- 3. *Role:* Do you or a member of your family serve as a director, trustee, officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of the University of Wisconsin-Oshkosh?
- 4. *Intellectual Property:* Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property owned or managed by the University of Wisconsin-Oshkosh, WiSys, or WARF.

Financial Disclosure:

- If you have answered **No** to all of the above questions, please sign below and submit this form to the Office of Grants and Faculty Development.
- If you have answered **Yes** to any of the above questions for yourself or a family member, please sign below and fill out the Financial Disclosure Section (Part II).
 - Part II. attached for: self family member

Certification:

I have read and understand the University of Wisconsin Oshkosh Office of Grants and Faculty Development policy on Conflict of Interest in Federal Research and have completed this report to the best of my knowledge and belief. If required, I will comply with any conditions or restrictions imposed by the University of Wisconsin Oshkosh to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my Family, change in a way that results in different answers to any of the questions asked in this report; I agree to submit a revision within 30 days. I have completed the required CITI Program Conflict of Interest Course and have attached my training certificate.

Signature

Date

CITI Training Reference #

Part II: Financial Disclosure

Instructions: This form should be filled out for each Investigator (including immediate family members) that has a financial interest in an entity. Please submit individual disclosures for each entity held by an individual. Additional financial disclosure forms are located on the Grants and Faculty Development website: www.uwosh.edu/grants/forms.

Reporting for: self family member (Please fill out one form for each entity held by each individual)

Investigator Name:
Role in Research Project:
Name of External Entity:
Address of External Entity:

Type of external relationship: (check all that apply)

- Consultant
- Speaker
- Advisory Board or Committee
- Equity Holdings
- Governing Board or Officer, Position held:
- Intellectual Property Rights (e.g., patents, copyrights, trademarks)
- Royalty Income
- Other :

Time:

Total amount of time spent (days) for reporting period:	
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Compensation:

Total amount of compensation or financial interest in reporting period:	\$
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Travel: (if paid by entity)

Destination:	
Amount:	\$
Comments or explanatory information:	

Investigator Signature

Date

Administrative Use Only Below This Line

Section A: Determination if Financial Conflict of Interest (FCOI) Exists: (to be determined by IO or their designee)

Is this a significant financial interest that relates to the Investigator's Institutional responsibilities? Yes No

If yes, the IO will appoint an ad hoc Research Responsibility Committee to determine if the conflict can be managed.

Comments:

Signature: _____

Date: _____

Section B: Determination if FCOI can be Managed: (to be filled out by ad hoc Research Responsibility Chair)

Date of Review:

Review Team:

Reviewer Comments: _____

Research Responsibility Committee Recommendation: Conflict is not Manageable Conflict is Manageable

The Office of Grants and Faculty Development are informed by the committee when a conflict is deemed unmanageable. The funding agency is notified if it is required and the award is not accepted.

If a conflict is deemed to be manageable, the committee prepares a Financial Conflict of Interest Management Plan for approval by the Institutional Official. Once the Investigator agrees to the terms of the plan, the award is accepted and the funding agency is notified if it is required.

Appendix B: Financial Conflict of Interest Management Plan

Part I: Management Plan

(Part I to be completed by Research Responsibility Committee)

Date of Review:	
Investigator:	
Grant Application Title:	
Grant Sponsor:	

Based on the facts as stated in the Financial Disclosure Form, the following actual, potential, or perceived conflicts of interest have been identified by the committee:

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What is the plan to manage, reduce, or eliminate the conflict of interest?

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How will the committee review the ongoing activity to ensure compliance with this plan?

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Review of the plan:

Quarterly Semi-annually Annually

Part II: Premises of Plan

1. Investigator has to the best of his/her ability, prepared a complete and accurate disclosure of financial interests.
2. Investigator has read and understands the Office of Grants and Faculty Development's Financial Conflict of Interest Policy and has completed the required CITI Training.
3. Investigator's activities include significant financial interests that are related to an Investigator's institutional responsibilities.
4. Investigator agrees to adhere to a Management Plan in order to manage actual, potential, or perceived conflicts of interest raised by activities in Investigator's disclosure.

Part III. Terms of Management Plan

1. Management plan shall be effective for a period of one year after which it must be updated annually
2. Management plan may be terminated under the following circumstances:
 - a. upon execution of a superseding management plan
 - b. at such time as Institution determines no further management plan is required under the Conflict of Interest Policy
 - c. if there is failure by Investigator to comply with the terms of the management plan

Part IV. Agreement of Management Plan

Investigator Certification: I have read and understand the University of Wisconsin Oshkosh Office of Grants and Faculty Development policy on Conflict of Interest in Federal Research. I will comply with any conditions or restrictions imposed in this plan to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my Family, change in any way that affects my institutional responsibilities; I will submit an addendum to my most recent Financial Disclosure Form within 30 days.

Investigator Signature

Date

Signatories:

Committee Chair

Date

Director of Office of Grants and Faculty Development

Date

Institutional Official or designee

Date

Appendix C: Retrospective Review

(Prepared if noncompliance with FCOI Policy is discovered)

Part I: Part I to be completed by Research Responsibility Committee

Date of Review:	
Investigator:	
Grant Application Title:	
Grant Sponsor:	

Description of the financial conflict of interest discovered by the Institution:

Was the research conducted during the period of noncompliance biased in the design, conduct, or reporting of the research?

Yes No Uncertain

Please explain:

Committee Chair Signature

Date

Part II: Part II to be completed by Institutional Official and Director of the Office of Grants and Faculty Development

Action Plan:	
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Is reporting to the funding agency required? (PHS agencies require submission of a Mitigation Report if bias is found)

Yes No

Director of Office of Grants and Faculty Development

Date

Institutional Official or designee

Date