



BTI

POLICY AND PROCEDURE

Financial Conflict of Interest

<i>Department:</i> General Corporate	<i>Category:</i> Integrity	<i>Policy No.:</i> 1.20.040	<i>Effective Date:</i> 08/23/2012	<i>Page No.:</i> 1 of 7
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Description: Boyce Thompson Institute for Plant Research (BTI) is required to maintain and enforce a written Financial Conflict of Interest (FCOI) policy that meets or exceeds federal regulatory requirements. This policy applies to each Investigator, as defined by the regulation, who is planning to participate in, or is participating in Public Health Service (PHS) funded research.

This policy is publicly available on our website at the following location:
<https://btiscience.org/translational-program/>

Policy: BTI is committed to promoting a FCOI policy which requires overseeing the conduct of research in a manner that ensures the integrity of the research process. This commitment requires BTI to ensure there is no reasonable expectation that research results are biased by the external commitments and financial interests of persons who are responsible for the design, conduct, reporting, or direct administration of BTI research. Such individuals are, for the purposes of this policy, referred to as "Investigators."

This policy and procedure defines key terms and outlines the roles and responsibilities of all involved parties.

Definitions: Disclosure of significant financial interests – An Investigator's disclosure of significant financial interests to an Institution.

Financial Conflict of Interest (FCOI) – A significant financial interest that an Investigator has (including their spouse/domestic partner and dependent children) that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

FCOI report – An Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest – Anything of monetary value, whether or not the value is readily ascertainable.

HHS – The United States Dept. of Health and Human Resources, and any components of the Dept. to which the authority involved may be delegated.

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 research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

PHS – The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including, but not limited to the National Institutes of Health (NIH).



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Significant financial interest (SFI) – A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse, including domestic partner, and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

- With regard to any publicly traded entity, a SFI 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;
- With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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 provided in regulation.

SFI exclusions – The following need not be considered for FCOI purposes:

- Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
 - Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- 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;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.



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Sub Recipient Investigator – Any party entered into an Agreement with BTI as a sub grantee, subcontractor, collaborator, contractor, or consultant.

BTI Responsibilities:

Records – Maintain records of all Investigator disclosures of financial interests and BTI's review of, and response to, such disclosures (whether or not disclosure resulted in BTI's determination of FCOI) and all actions under BTI's policy or retrospective review, if applicable.

- For at least 3 years from the date of submission of the final expenditures report, or where applicable.
- From other dates specified in [45 C.F.R. 74.53\(b\)](#) and [92.42\(b\)](#) for different situations.

Application Certification – Each application for funding must include the following:

- An up-to date written and enforced administrative process to identify and manage FCOI's related to all PHS research projects.
- Promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFI's.
- Agree to make information available upon request relating to any Investigator disclosure of financial interest and BTI's review of, and response to, such disclosure, whether or not the disclosure resulted in BTI's determination of an FCOI.
- Manage FCOI's and provide initial and ongoing FCOI reports to PHS/NIH, which is accessed online via [eRA Commons](#). This website allows the following:
 - Electronic submission of FCOI reports and supporting documents
 - Submission of annual FCOI report
 - Submission of additional information when requested by the agency
 - Ability to search and view FCOI reports and associated data previously submitted through the Commons
 - Fully comply with the requirements of the regulation.

Designated Institutional Official(s)

- The Chief Financial Officer and Human Resource Manager are the individuals designated as Institutional Officials to solicit & review disclosure statements from each Investigator planning to participate in, or is participating in, PHS/NIH-funded research
- Provide guidelines to identify conflicting interests related to proposed or PHS/NIH-funded research
- Designated Institutional Official(s) develop management plans that specify the actions that have been, and shall be, taken to manage FCOI

Inform Investigators

- Must inform each Investigator of the:
 - Regulation;
 - Institution's policy on FCOI; and
 - Investigator's responsibilities regarding disclosure of SFIs



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Investigator Training – Institutions must require that each Investigator complete FCOI training:

- Prior to engaging in research related to any NIH funded project;
- At least every four years, and
- Immediately when any of the following circumstances apply:
- Institution revises its policy in a manner that affects the investigator;
- When an Investigator is new to the Institution; or
- When the Institution finds an Investigator is not in compliance with the Institution's policy or management plan.

Investigator Disclosure of SFIs

- *At time of Application:* Require that each Investigator, including sub recipient Investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application.
- *Annually:* Require each Investigator, including sub recipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award.
- *Within 30 days:* Require each Investigator, including sub recipient Investigator, if applicable, who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Management of FCOIs

- Take necessary actions to manage FCOIs of its Investigators, including those of sub recipient Investigators
- Develop a management plan(s) and monitor compliance
- If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed.
- In cases of noncompliance, complete a retrospective review and submit a Mitigation Report if bias is found.

FCOI Reporting

- Provide initial and ongoing FCOI reports to NIH:
 - Prior to the expenditure of funds
 - During the period of award
 - Within 60 days of identifying a new FCOI
 - Annually
 - Report on the status of FCOI and any changes in management plan
- Due at same time as when grantee submits annual progress report, including multi-year progress report, or at time of extension
- All FCOI reports are submitted to NIH through the Electronic Research Administration (eRA) Commons FCOI Module.
 - Reporting tool for submitting FCOI reports for grants and cooperative agreements



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- Existing reporting tool is being enhanced.

Public Accessibility of FCOIs

- Prior to expenditure of funds, make certain information concerning FCOIs held by senior/key personnel publicly accessible via a Web site or provide written response within five business days of a request.
 - Update the website annually and within 60 days of identifying any new FCOIs when posting FCOIs to website
 - Retain information for three years

Retrospective Review

- The Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the investigator's activities and the NIH-funded research project to determine if there was bias in the design, conduct, or reporting of such research. Institution is required to document the retrospective review.
 - A Mitigation Report required if bias is found.
- Notify NIH promptly and submit a Mitigation Report when bias is found.

Mitigation Report

- If bias is found through retrospective review, notify the NIH Awarding Component promptly (through the eRA Commons) and submit a Mitigation Report.
- Thereafter, submit FCOI reports annually.

Enforcement

- Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance.

Investigator Responsibilities:

FCOI training is required with the new regulation. Each Investigator must complete training prior to engaging in research related to any NIH-funded grant and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.

Investigators are responsible for disclosing significant financial conflicts of interest to the Institution.

NIH Responsibilities:

[A tutorial \(created by NIH\)](#) will be used as a reference guide for BTI's FCOI policy and shall support and supplement our training program. There are review questions and a certificate of completion can be printed at the end.

- If the failure of an Investigator to comply with the Institution's FCOI policy or FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution shall promptly notify the



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NIH of the corrective action taken or to be taken.

- NIH may determine that corrective action is needed and may include directions to the Institution on how to maintain appropriate objectivity in NIH-funded research.
- NIH may require Institutions employing such an Investigator to enforce any applicable corrective actions prior to award or when the transfer of a grant involves such an Investigator.
- NIH may inquire at any time before, during or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a FCOI.
- Institutions are required to submit, or permit on site review of, all records pertinent to compliance with the regulation.
- NIH will maintain confidentiality of all records of financial interest.
- If NIH decides that a particular FCOI will bias the objectivity of research, NIH may impose special award conditions, suspend funding or impose other enforcement mechanisms until the matter is resolved.
- In any case in which NIH determines that an NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by regulation, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

**Additional
References:**

Electronic Code of Federal Regulations:

<https://gov.ecfr.io/cgi-bin/ECFR>

NSF FCOI Policy:

https://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp#IVA

NIH FCOI Policy:

<https://grants.nih.gov/grants/policy/coi/index.htm>

NIH website FCOI FAQ's (periodically updated):

<https://grants.nih.gov/grants/policy/coifaq.htm>

NIH Office of Extramural Research FCOI Web Site:

<https://grants.nih.gov/grants/policy/coi/index.htm>



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**FCOI Regulation
Contact
Information:**

For questions regarding the FCOI regulation:

Kathy Hancock
Assistant Grants Compliance Officer
Division of Grants Compliance and Oversight, OPERA, OER
301-435-1962
kathy.hancock@nih.gov

General FCOI inquiries:
FCOICompliance@mail.nih.gov

For questions regarding FCOI module:
eRA Commons Help Desk
Web: <http://era.nih.gov/help/> (Preferred method of contact)
Toll-free: 1-866-504-9552
Phone: 301-402-7469
TTY: 301-451-5939
Hours: Mon.-Fri., 7a.m. to 8 p.m. Eastern Standard Time
Email: commons@od.nih.gov (for Commons Support)