



POLICY FOR PROMOTING OBJECTIVITY
IN BIOMEDICAL RESEARCH

AUGUST 24, 2012

**BROOKHAVEN NATIONAL
LABORATORY
POLICY FOR PROMOTING OBJECTIVITY
IN BIOMEDICAL RESEARCH***

I. Purpose

Brookhaven National Laboratory (herein referred to as “the Laboratory”) receives funds from the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies. All investigators (as defined below) applying for funds from the NIH or other PHS agencies are obliged to comply with the requirements of the Laboratory’s Policy for Promoting Objectivity in Biomedical Research, also referred to as the Financial Conflict of Interest Policy (FCOI).

Specifically, all United States Public Health Service agencies (includes National Institutes of Health, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Food and Drug Administration and the Agency for Healthcare Research and Quality) require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought issued at 42 CFR Part 50, Subpart F (the “FCOI Regulations”) and “Responsible Prospective Contractors” issued at 45 CFR Part 94 (see the [NIH Financial Conflict of Interest](#) web page). For purposes of this FCOI Policy, all references to “PHS” shall be a reference to the respective PHS funding agency.

The FCOI Regulations covering PHS funded activities provide for a more comprehensive level of disclosure, together with compulsory reporting to the applicable PHS agency. Disclosure to the Laboratory is required of ALL “Significant Financial Interests” that reasonably appear related to the investigator(s) “Institutional Responsibilities.”

“Institutional Responsibilities” means an investigator’s professional responsibilities on behalf of the Laboratory, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards.

“Investigator(s)” means PIs, co-PIs, key personnel who are responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, which may include, for example, consultants, postdocs, graduate students, and unpaid collaborators)

II. Guidance for Implementation

The Laboratory is responsible for ensuring that each investigator is informed about (i) this FCOI Policy, (ii) the investigator’s responsibilities regarding disclosure of significant financial interests relating to the investigator’s institutional responsibilities, and (iii) the FCOI Regulations. The Laboratory requires each investigator to complete training regarding items (i)–

(iii) prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every four (4) years thereafter, and immediately when any of the following applies: (1) this FCOI Policy, the BNL Disclosure Statement Form or Laboratory procedures are revised in any manner that affects the requirements of the investigators; or (2) the Laboratory finds that an investigator is not in compliance with this FCOI Policy.

III. Disclosure Procedures

- a. All investigators are required to disclose financial interests via the Laboratory's [BNL PHS Disclosure Form](#) at the time any PHS application is submitted. The lead principal investigator on a proposed PHS application for funding is responsible for obtaining a BNL PHS Disclosure Form for all participating investigators.
- b. The PHS Disclosure Form shall ask the investigator to list all of his/her significant financial interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the investigator's institutional responsibilities.

“Significant Financial Interest” means (subject to the exclusions listed below):

- (i) Publicly Traded-Entities - With regard to any publicly traded entity, 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. 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.
- (ii) Privately Held Entities - With regard to any non-publicly traded entity, a significant financial interest exists if any remuneration was *received from the entity in the twelve months preceding the disclosure*, or when the investigator (or the investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
- (iii) Intellectual Property - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (iv) Travel Reimbursements - Investigators also 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 *in the twelve months preceding the disclosure*; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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.

The term “significant financial interest” does not include: salary, royalties, or other

remuneration paid by the Laboratory to the investigator if the investigator is currently employed or otherwise appointed by the Laboratory, including intellectual property rights assigned to the Laboratory and agreements to share in royalties related to such rights; 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, 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.

- d. In addition, the investigator must cooperate with all requests from the applicable PHS Awarding Component for additional information as needed. All such internal disclosures shall be treated as confidential personal information with all necessary precautions to protect any sensitive proprietary company or sponsor information.
- e. The investigator shall update the disclosure of significant financial interest during the period of the award, at least annually, in accordance with the specific time period prescribed by the Laboratory. One annual disclosure will suffice to cover all on-going PHS awards. With respect to transfers, an annual disclosure shall be made to the Laboratory promptly to support acceptance of the appointment or employment to the Laboratory. The reporting and management plan requirements described in Article V shall then be required to be completed prior to expending any funds under a PHS funded grant, cooperative agreement or contract. In addition, an investigator participating in PHS-funded research shall submit an updated PHS Disclosure Form within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest. An investigator who is new to participating in PHS-funded activities shall submit a PHS Disclosure Form at the time the investigator is identified as a possible participant in a PHS-funded research project, such that training can be completed and timely reporting of a FCOI (if any) can be made to the respective funding agency.
- f. All disclosures are required to be reviewed by the designated institutional official(s) in a prompt manner such that within sixty (60) days of receipt of the disclosure an assessment of the significant financial interest can be made, a management plan can be developed and all the necessary reviews and approvals can be secured, such that any required report to the applicable PHS funding agency is submitted within sixty (60) days of the determination that a FCOI (as defined in Article IV below) exists. The investigator's timely cooperation with the efforts of the designated institutional official(s) is needed to ensure timely reporting. Upon a failure to make timely reporting to the PHS funding agency of a FCOI, the Laboratory is required under the FCOI Regulations to conduct a retrospective review of the investigator's activities and the research project.

IV. Management of Financial Conflicts of Interests

- a. The Work For Others Management Systems Executive is the designated Laboratory official who reviews all BNL PHS Disclosure Forms; determine whether an investigator's significant financial interest is related to PHS- funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.
- b. The following are examples of when an investigator would be deemed to have a financial conflict of interest: (i) if the investigator (together with investigator's spouse or dependent children) has a significant financial interest in an entity that could be affected by the research results from a proposed PHS-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application, or (ii) the investigator (together with investigator's spouse and dependent children) has a significant financial interest in an entity that licenses technology from the Laboratory which has resulted in license income and that technology is the subject of a proposed PHS-funded award. In making this determination, the designated institutional official(s) may consult with all appropriate institutional and governmental officials.
- c. Following initial review all cases involving the disclosure of significant financial interest shall be submitted to Legal. Legal decides upon one of the following dispositions of the case: approval, approval with conditions or restrictions, or prohibition. All conflicts which are approved shall include a management plan and shall be monitored and implemented by an oversight committee.
- d. For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of significant financial interests; (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts; (7) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants is required.
- e. For all management plans, the Laboratory monitors investigator compliance with the management plan on an on-going basis until the completion of the PHS-funded research project.

V. Reporting Financial Conflicts of Interests to PHS

- a. Prior to expending any funds under an PHS funded grant, cooperative agreement or contract, the Laboratory reports to the applicable PHS funding agency the existence of any significant FCOI (as defined in Article III above) and assures that the Laboratory has implemented a management plan in accordance with the PHS FCOI Regulations. If the

Laboratory identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the Laboratory is not required to submit a FCOI report to the respective agency. The requirements of the FCOI Regulations do not apply to PHS funded Phase I SBIR or STTR funding.

- b. The Laboratory files an annual report that conforms to the requirements of the FCOI Regulations for the duration of the research project in the time and manner specified by the applicable funding agency.
- c. For any significant financial interest that the Laboratory identifies as being a FCOI subsequent to the Laboratory's initial FCOI report under the award, the report will be made to the applicable funding agency and a management plan shall be implemented, at least on an interim basis, within sixty (60) days of that identification. Such a disclosure could include a new significant financial interest received by the investigator during the on-going research project, or a significant financial interest held by an investigator who is new to the research project. However, if that FCOI is one that was not timely made to the applicable funding agency, for whatever reason, the Laboratory is required under the FCOI Regulations to conduct a retrospective review of the investigator's activities and the research project. If bias is found during the course of this review, a mitigation report is required to be submitted. These reviews and reports must be made in accordance with the requirements of the FCOI Regulations.
- d. The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations. The FCOI Regulations provide that, to the extent permitted by law, the Government will maintain the confidentiality of all records of financial interests.
- e. Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the Laboratory shall ensure public accessibility via a written response to any requestor within five (5) business days of a request, of information concerning a significant financial interest which was disclosed the meet the following three criteria:
 - (1) The significant financial interest was disclosed and is still held by the senior/key personnel on the project
 - (2) The Laboratory determines that the significant financial interest is a financial conflict of interest, and
 - (3) The Laboratory determines that the significant financial interest is a financial conflict of interest.

The information shall consist of the information required to be provided under the FCOI Regulations.

VI. Subrecipient Compliance and Reporting

- a. All proposed subrecipients under a PHS-funded research of the Laboratory shall have a financial conflicts of interest policy that conforms to the requirements of the FCOI Regulations. With respect to these subgrantees, subcontractors, and collaborators, the Laboratory requires these entities to enter into a written agreement and make a certification to

the Laboratory at the time of award that its financial conflicts of interest policy complies with the FCOI Regulations. The written agreement shall include all of the terms required under the FCOI Regulations.

- b. The Laboratory will report to the PHS funding agency any FCOI which are identified by any subgrantee, subcontractor, or collaborator to the Laboratory in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

VII. Remedies

- a. If an investigator fails to comply with this FCOI Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS- funded research, the Laboratory, as required under the FCOI Regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, the Laboratory shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations. The funding agency may take its own action as it deems appropriate, which may include suspension of funding, or require the Laboratory to take further action to maintain the objectivity of the research.
- b. For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the Laboratory requires the investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

VIII. Enforcement and Sanctions

- a. All persons subject to this FCOI Policy and other applicable Laboratory policies are expected to comply fully and promptly. Whenever an investigator has violated the Laboratory's FCOI Policy, for example, by a failure to disclose a significant financial interest, the Laboratory may refer the matter to the appropriate Laboratory official or committee for disciplinary action or other appropriate action.
- b. Violations of the Laboratory's FCOI Policy and the FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the respective Laboratory policy and procedures governing allegations of research misconduct.
- c. Although repercussions to the Laboratory are not stated in the new regulations, it is plausible that a significant under-reporting could impact on-going and future programs and, if by the same staff member, damage her or his reputation for consideration for future awards.

IX. Records

The Laboratory is required pursuant to the FCOI Regulations to maintain all PHS Disclosure Forms and all related records of actions taken by the Laboratory with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

CONFIDENTIAL

*****This document is confidential and cannot be copied once completed*****

**BROOKHAVEN NATIONAL LABORATORY DISCLOSURE STATEMENT
UPON APPLICATION FOR A SPONSORED PROGRAM GRANT OR CONTRACT FROM
PUBLIC HEALTH SERVICE AGENCIES**

Name

Title of Position

Department

Sponsor

Title of Proposal or Project

Date of Application

The purpose of this form is to promote transparency and objectivity in research by disclosing significant financial interest (SFI) of investigators and key project personnel. Disclosure may include that for spouse and dependent children. This form applies to investigators and key project personnel which includes project directors, principal investigators and co-PIs, collaborators, consultants, post-docs and graduate students who are responsible for the design, conduct or reporting of research funded by the PHS.

Refer to BNL's POLICY FOR PROMOTING OBJECTIVITY IN BIOMEDICAL RESEARCH for more information.

Reminder: Disclosure applies to information that reasonably appears to be related to the investigator's Laboratory responsibilities.

Please answer the following questions:

1. Publicly Traded-Entities - With regard to any publicly traded entity, a significant financial interest exists if any remuneration is received from the entity in the twelve months preceding the disclosure and if there is any equity interest in the entity as of the date of disclosure. 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. *Does not include mutual funds investments and retirement accounts which the investigator does not control.*

Please provide information for investigators/self:

Name of Organization	Address	Investment or Position	Description

2. Privately Held Entities - With regard to any non-publicly traded entity, a significant financial interest exists if any remuneration is received from the entity in the twelve months preceding the disclosure or when the Investigator (or the Investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) in the entity.

Please provide information for investigators/self, spouse and dependent children:

Identify Self, Spouse, Dependent Children	Name of Organization	Address	Investment or Position	Description

3. List name and describe the nature of any current employment or occupation of spouse or dependent children that is related to the area of research that is the subject of this application.

Please separately list any significant financial interest held by your spouse or your dependent children with any firm, corporation, association, partnership or other organization that is involved in the area of research that is the subject of this application.

Identify Self, Spouse, Dependent Children	Name of Organization	Address	Investment or Position	Description

4. Any reimbursement or sponsored travel paid by an entity, including non-profit organizations. Excludes travel sponsored by BNL/BSA, or reimbursed by a government agency, a U.S. institution of higher education or a research institute affiliated with such, a medical center, or an academic teaching hospital.

Please provide information for investigators/self:

Organization Sponsoring Travel	Purpose of Travel	Destination	Duration of Travel (exact dates not necessary)

5. Identify income from intellectual property rights and interests (e.g. patents, copyrights). Excludes intellectual property rights assigned to BNL/BSA and its royalties that flow to the investigator.

6. I agree:

- To update this disclosure during the proposal award period or during the project as new significant financial interests are obtained by me or my spouse or dependent children. I will do this within thirty (30) days of acquiring or discovering such significant financial interest.
- To cooperate in the development of a management plan, if needed.
- To comply with any conditions or restrictions imposed by Brookhaven Science Associates to promote objectivity in research and manage, reduce, or eliminate actual or potential conflicts of interest.

Signature

Date

Disposition of Review (By Designated Institutional Official)

I have reviewed the above information and the referenced proposal and to the best of my knowledge find no evidence of conflict of interest or the appearance thereof.

OR

I have reviewed the above information and the referenced proposal and to the best of my knowledge find that a significant financial interest requires a management plan and/or a possible conflict of interest or the appearance thereof. Details are attached.

Therefore, circle as applicable:

1. The P and/or key/senior staff has been notified that s/he must resign from or relinquish the conflict prior to resuming work on the Project.
2. A management plan has been created to address the conflict that:
 - a. Describes role and duties of PI and/or senior/key personnel.
 - b. Sets forth how the management plan will safeguard the objectivity NIH project performance and reporting.
 - c. Sets forth how the management plan will be monitored.
 - d. Provides other information as necessary.
3. Has been accepted by the PI or senior/key personnel

Michael J. Furey, Manager
Research Partnerships
Work For Others Management Systems Executive

Date

Sample Management Plan

Name (Printed)
Title of Position
Department
NIH Institute/Center Receiving Proposal
Title of Proposal or Project
Date of Application

1. Role and duties of PI and/or senior/key personnel.

2. How the management plan will safeguard the objectivity NIH project performance and reporting.

3. How the management plan will be monitored.

4. Other information as necessary.
