



Investigator Financial Conflicts of Interest (Including Specific Requirements for Public Health Service (“PHS”) Funded Grants and Cooperative Agreements)

I. Purpose:

This Policy promotes objectivity in research by establishing standards to provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest (“FCOI”). If an Investigator FCOI exists, the New York Blood Center (“NYBC”) will manage, reduce, or eliminate the financial conflict of interest pursuant to this Policy. Appropriate management of FCOI is important to support the institutional goals of NYBC. This Policy also addresses requirements of 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, related to Public Health Service (“PHS”) research funding that the Institution may apply for or receive. This Policy will be made available to the public via NYBC’s website.

II. Scope:

This Policy applies to all NYBC employees who are Investigators (as that term is defined below), including employees who are applicants for, or recipients of, PHS-funded grants or cooperative agreements, and those that are not. As applicable and described below, the Policy also applies to subrecipients, independent contractors, and agents acting on behalf of NYBC and participating in Research, as defined in this Policy. SBIR Program Phase I applications are *not* considered PHS-funded grants or cooperative agreements for purposes of this Policy.

III. Timing of Application of this Policy to Investigators:

This Policy has an effective date of August 24, 2012. All Investigators must receive immediate training. The terms of the Policy otherwise will be applied in the following manner to Investigators who are currently employed at NYBC before August 24, 2012:

- For Investigators seeking, but not yet the recipient of, a PHS-funded grant or cooperative agreement, this Policy shall apply if the Notice of Award is dated on or after August 24, 2012.
- For Investigators who are recipients of an ongoing PHS-funded grant or cooperative agreement for which a Notice of Award was dated before August 24, 2012, the Policy shall apply as of the date of submission of each application for Continuing Renewal of the PHS-funded grant or cooperative agreement, and then for the duration of the grant or agreement.

- For Investigators who are not seeking or are the recipients of PHS-funded grants or cooperative agreements on or after August 24, 2012, this Policy shall apply on the next anniversary date (or the first business day immediately following the anniversary date) of the Investigator’s employment by NYBC.

For Investigators who begin employment by NYBC on or after August 24, 2012, this Policy shall be applicable upon employment.

IV. Definitions:

- A. **Financial Conflict of Interest** (“FCOI”) means any significant financial interest requiring disclosure under this Policy and that NYBC, through its Institutional Official, reasonably determines could directly and significantly affect the design, conduct, or reporting of research.
- B. **Institution** means the New York Blood Center, Inc. (“NYBC”). The terms Institution and NYBC are used interchangeably in this Policy.
- C. **Institutional Official** (“IO”) means the person appointed by NYBC, or his/her delegate(s), responsible for the oversight and implementation of this Policy. This includes (without limitation) responsibility for the solicitation and review of information from Investigators concerning significant financial interests requiring disclosure. NYBC has appointed the Executive Director of the Office of Sponsored Programs as its Institutional Official. In reviewing and making determinations concerning Investigator disclosures per this Policy, the IO will act in consultation with a committee comprised of (1) a representative from NYBC’s Law Department, and (2) the appropriate executive supervisor for the Investigator.
- D. **Investigator** means the project director, principal investigator, collaborators, consultants, and any other member of a research team, regardless of title or position, who is responsible for the design, conduct, or reporting of research.
 - 1. The term Investigator is broader than the term “*senior/key personnel*,” the latter meaning the project director or principal investigator and any other person identified by NYBC as senior/key personnel in a grant application, progress report, or other report submitted to PHS.
- E. **Institutional Responsibilities** shall mean, as determined by the IO, those activities conducted on behalf of the Institution by an Investigator, including research, activity as a consultant, teaching, professional practice, administrative duties, committee memberships, and service on panels.
- F. **Manage** means taking action to address an Investigator’s FCOI, which can include reducing or eliminating the FCOI, to provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias related to the FCOI.
- G. **PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which authority may be delegated, including the National Institutes of Health (“NIH”).

H. **Research** means any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses *basic and applied research* as well as product testing and development. The term includes, but is not limited to, any activity for which research funding is available from a PHS component that awards funds under grants, cooperative agreements or otherwise, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, research resources award or contract.

I. **Significant Financial Interest** (SFI) means:

1. The following financial interest(s) held by the Investigator (or the Investigator's spouse/domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities:

a) With respect to a publicly traded entity, a SFI exists if any *remuneration* received from the entity in the *12 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*.¹

b) With respect to a non-publicly traded entity, a SFI exists if any *remuneration* received from the entity in the *12 months preceding* the disclosure, when aggregated, *exceeds \$5,000*.

c) With respect to a non-publicly traded entity, a SFI exists if an Investigator (or the Investigator's spouse/domestic partner or dependent children) holds any *equity interest* in a non-publicly traded entity.

d) *Intellectual property rights and interests* (e.g., patents, copyrights), upon receipt of income related to such rights and interests (e.g., fees or royalties).

2. Travel that has been reimbursed or sponsored (i.e., that has been paid on behalf of an Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to Institutional Responsibilities. The Investigator's disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The IO may determine that further information is needed (e.g., determination of monetary value) in order to determine whether the travel constitutes an FCOI.

a) 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

¹ For purposes of the SFI 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.

academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

3. The term SFI *does not* include the following types of financial interests:

a) Salary, royalties, or other remuneration paid by NYBC to the Investigator if the Investigator is currently employed or otherwise appointed by NYBC. This includes intellectual property rights assigned to NYBC and agreements to share in royalties related to such rights.

b) 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.

c) 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.

d) 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.

V. Policy:

A. General

NYBC, through the Institutional Official, will require adequate disclosures by Investigators to enable the Institution to identify SFI related to proposed and ongoing research. If the IO determines that an Investigator has a Financial Conflict of Interest, then NYBC, through the IO, will manage, reduce, or eliminate the FCOI. In addition, NYBC, through the IO, will: maintain records related to FCOI reviews and related actions; prepare and submit any required reports, statements, or certifications; and respond to inquiries or other communications from third parties with respect to FCOI.

B. Informing and Training Investigators

Each Investigator must be informed of this Policy on FCOI, the Investigator's responsibilities regarding disclosure of SFIs, and the requirements of 42 CFR Part 50 and 45 CFR Part 94. Each Investigator must complete training: (i) *prior to* engaging in research at or sponsored by NYBC, (ii) at least every 4 years, and (iii) *immediately* under the following circumstances:

1. When this Policy is revised by NYBC in a manner that affects Investigator requirements;
2. When an Investigator arrives to conduct research at NYBC; and

3. When NYBC determines that an Investigator is not in compliance with this Policy or an FCOI management plan.

C. Investigator Disclosure of Significant Financial Interests

1. *Routine Disclosure:*

Investigators must disclose all SFI related to their Institutional Responsibilities, in the manner determined by the IO:

- a) At the time of employment prior to the conduct of any research whether PHS-funded or not;
- b) No later than the time of each application for PHS-funded research; and
- c) At least *annually*, during the period of the research.

2. *Mandatory Updates to Disclosures:*

Each Investigator must submit an updated disclosure of SFI *within 30 days of discovering or acquiring* a new SFI (e.g., through purchase, marriage, or inheritance).

In addition, following an Investigator's initial disclosure of SFI to the Institution, each updated disclosure of SFI (e.g., new application, annual update) must include:

- a) Any information that was not disclosed initially or in a subsequent disclosure (e.g., any FCOI identified on a PHS-funded project that was transferred from another institution).
- b) Updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

D. Identification of SFI That Create "Financial Conflicts of Interest"

For administrative purposes of this Policy, all SFI will be presumed to be related to an Investigator's research. It is the responsibility of the Institutional Official to determine whether a SFI disclosed by an Investigator creates a Financial Conflict of Interest with respect to that research.

- ***A FCOI exists when NYBC, through the IO, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.***

It is *not* the responsibility of the Investigator to determine whether a SFI is related to research or is a Financial Conflict of Interest. The IO may, however, involve the Investigator in elucidating the nature of a SFI, to support the IO's analysis.

The IO will notify the affected Investigator if the IO determines that an FCOI exists.

E. Management of Financial Conflicts of Interest

1. *Procedure to Establish (and Update) Management Plan:*

If an FCOI exists, the IO shall develop a written management plan (“Management Plan”) that specifies actions that have been, and will be, taken to manage such FCOI.

The IO will provide the affected Investigator with a copy of the Management Plan. If the Investigator believes that the Management Plan fails to reasonably manage a FCOI, the Investigator may propose a specific revision and justification to the IO. If the IO does not respond in a manner that adequately addresses the Investigator’s concern, the Investigator may seek review of the matter by NYBC’s CEO. The determination of the CEO will be binding on NYBC and the Investigator.

As discussed in Section IV.C. of this Policy, new SFI disclosures may occur during the course of ongoing research (e.g., addition of a new Investigator; current Investigator identifies a new SFI, or identifies a SFI that should previously have been disclosed). In that event, within sixty (60) days following an Investigator’s new disclosure of a SFI to the IO, the IO shall determine whether an FCOI exists and whether the Management Plan should be temporarily or permanently modified.²

2. *Content of a Management Plan:*

As appropriate, the IO shall develop a Management Plan that establishes the steps by which the objectivity of research can be reasonably assured. If the IO determines it appropriate in certain circumstances, it may be acceptable that no specific mitigation steps are imposed. Otherwise, the components of a Management Plan may include, but are not limited to:

- Public disclosure of an Investigator’s FCOI (e.g., when presenting or publishing the research);
- For research involving human subjects, disclosure of Investigator FCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from an Investigator’s financial interest;
- Modification of the research plan;
- Change in personnel or personnel responsibilities, or disqualification of an Investigator from participating in all or a portion of any research;
- Reduction or elimination by an Investigator of a financial interest; and/or
- Severance of any relationships that created the FCOI.

3. *Monitoring:*

² Temporary management controls may be imposed, if the IO deems it appropriate, pending full development or review of the full Management Plan.

An Investigator's compliance with a management plan is subject to ongoing monitoring by the IO and Institution.

VI. Additional Requirements For PHS-Funded Research Only:

The provisions of this Policy section pertain *only* to PHS-funded grants and cooperative agreements, in order to satisfy regulatory requirements specifically applicable to such research.

A. Reporting Financial Conflicts of Interest to PHS Awarding Component - Applicable Only to PHS-Funded Research

Prior to NYBC's expenditure of any funds under a PHS-funded research project, NYBC must provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by NYBC to be a FCOI and ensure that NYBC has implemented a management plan, as follows:

1. In cases in which NYBC identifies an FCOI and eliminates it *prior to* the expenditure of PHS-awarded funds, NYBC need *not* submit an FCOI report to the PHS Awarding Component.
2. For any SFI that NYBC identifies as an FCOI subsequent to NYBC's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), NYBC shall provide to the PHS Awarding Component, within *60 days*, an FCOI report to ensure that NYBC has implemented a *management plan*. Where such FCOI report involves an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by NYBC (e.g., was not timely reviewed or reported by a subrecipient), NYBC also is required to complete a *retrospective review* to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research.
3. Additionally, if bias is found, NYBC is required to *promptly notify* the PHS Awarding Component and submit a *mitigation report* to the PHS Awarding Component.

For any FCOI previously reported by NYBC with regard to ongoing PHS-funded research, NYBC shall provide to the PHS Awarding Component an *annual FCOI report* that addresses the status of the FCOI and any changes to the *management plan* for the duration of the PHS-funded research project. The annual FCOI report shall state whether the FCOI is still being managed or explain why the FCOI no longer exists.³

As required by federal regulations, NYBC shall report the following information regarding FCOI to the funding agency through the eRA Commons:

- Project Number
- PD/PI (or Contact PD/PI if multiple PD/PI model is used);

³ NYBC shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Nature of the FCOI (e.g. equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value;
- A description of how the financial interest relates to the PHS-funded research and the basis for NYBC's determination that the financial interest conflicts with such research; and;
- A description of key elements of NYBC's management plan including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed or requested by the funding agency.

B. Retrospective Review - *Applicable only to PHS-Funded Research*

Pursuant to Section IV.E.1. of this Policy, in the event that NYBC identifies a SFI not timely disclosed by an Investigator, or not previously reviewed to determine whether it creates a FCOI, the IO shall within 60 days determine whether a FCOI exists, and what prospective management steps will be imposed.

In addition, whenever an FCOI is not identified or managed in a timely manner (including failure by the investigator to disclose SFI that is determined to constitute an FCOI, failure by NYBC to review or manage such an FCOI, or failure by the Investigator to comply with an FCOI management plan), NYBC shall, within *120 days* of NYBC's determination complete a *retrospective review* of the Investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time was biased in design, conduct, or reporting of such research.

A retrospective review shall include, at minimum, the following information:

- Project number;
- Project title;
- PD/PI (or contact PD/PI if a multiple PD/PI model is used);
- Name of Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;

- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, NYBC shall specify in writing the actions to be taken to manage the FCOI going forward, notify the Investigator, and obtain the Investigator's written confirmation of his/her understanding of actions to be taken. For PHS-funded grants, NYBC shall also update the FCOI report previously submitted to PHS Awarding Component, specifying the actions that will be taken to manage the FCOI going forward.

C. Mitigation Report - *Applicable only to PHS-Funded Research*

If a retrospective review finds bias, NYBC must notify the PHS Awarding Component and submit a mitigation report in accordance with applicable regulatory requirements. Depending on the nature of the FCOI, NYBC may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project.

The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of bias on the research project, and NYBC's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis whether the research project is salvageable).

Thereafter, NYBC will submit to the PHS Awarding Component FCOI reports annually, as specified elsewhere in this Policy.

D. Additional Corrective Actions - *Applicable only to PHS-Funded Research*

If the failure of an Investigator to comply with NYBC's FCOI Policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, NYBC shall *promptly notify* the PHS Awarding Component of the corrective action taken or to be taken.

In any case in which the HHS 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 has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by NYBC as required, NYBC 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.

E. Applicability to Subrecipients - *Applicable Only to PHS-Funded Research*

For research sponsored by PHS that involves subcontractors, subgrantees or subawardees (collectively "subrecipients") at other institutions, NYBC requires a written agreement from subrecipients that establishes whether NYBC's Policy or the subrecipient's policy shall apply to

the subrecipient's Investigators. In all cases, NYBC must report to the PHS funding agency any subrecipient FCOI prior to the execution of the subcontract or within *60 days* of identification of a new FCOI by the subrecipient or NYBC that arises during the term of the subcontract.

1. If the subrecipient's Policy is used, the subrecipient must certify that its FCOI Policy is compliant with 42 CFR Part 50 and 45 CFR Part 94, and the subrecipient will be responsible for ensuring that the subrecipient's institution and its Investigators comply with the federal regulations. Subrecipients must report to NYBC as the awardee institution, any identified FCOI within *10 business days* of the *management plan* agreement with the subrecipient's Investigator, but no later than *45 days* after identification of the FCOI by the subrecipient. The details of the FCOI will be reported to the funding agency as required under applicable regulations or Policy.
2. If NYBC's Policy is used, the subrecipient must ensure that its Investigators submit the Significant Financial Interests Disclosure Statement (Form 9-34) to NYBC at the time of application by NYBC or at the time the subrecipient signs an institutional letter of support if during an ongoing award grant or contract.

F. Public Accessibility to Investigator Financial Conflict of Interest Information -
Applicable Only to PHS-Funded Research

Upon written request and to the extent required by law, NYBC will provide written information related to financial conflict of interest management to a requestor. Requests must be received in writing and must identify the specific PHS project number. The request must include a named recipient and return address with a physical street address; P.O. Boxes are not acceptable. NYBC will note in its written response that the information is current as of the date of the correspondence, and is subject to updates at least annually and within 60 days of NYBC's identification of a new conflict of interest, which must be requested under separate cover by the requestor. The following information generally will be provided in a written response:

- Project Number;
- Name of the Investigator with an FCOI;
- Investigator's title and role with respect to the research project;
- Nature of the FCOI (e.g. equity, consulting fee, travel reimbursement, honorarium); and
- Value of the FCOI (in dollar ranges), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value.

VII. Maintenance of Records:

The IO shall be responsible for maintaining records, identifiable to each project, concerning reports of SFIs and actions taken to manage any FCOI. For both PHS-funded research and research not funded by PHS, such records shall be maintained in accordance with applicable regulations and NYBC's Records Management Policy.

VIII. Enforcement of Policy:

Potential violations of this Policy should be immediately reported to the IO or the Law Department. If allegations of potential violation relate to an Investigator, the IO will investigate. If allegations of potential violation relate to the IO, the Law Department will investigate. If it is determined that a person has violated the Policy, that person will be subject to appropriate corrective and disciplinary action, up to and including termination of employment.