
NEW YORK STRUCTURAL BIOLOGY CENTER, INC.

Financial Conflicts of Interest Policy

Applicable to Federally Funded Research (42 C.F.R. Part 50, Subpart F)

1. Purpose

The New York Structural Biology Center, Inc. (NYSBC) is committed to maintaining objectivity in research and ensuring that the design, conduct, and reporting of research funded by the U.S. Public Health Service, as defined under 42 U.S.C. § 201 et seq., (PHS) and other federal agencies is free from bias arising from financial conflicts of interest. This Policy establishes standards for identifying, disclosing, reviewing, managing, and, where necessary, eliminating financial conflicts of interest (FCOIs) in federally funded research, in accordance with 42 C.F.R. Part 50, Subpart F and applicable NIH requirements.

2. Scope

This Policy applies to all Investigators (as defined below) engaged in the design, conduct, or reporting of research funded in whole or in part by the PHS, the National Institutes of Health (NIH), or any other federal agency that has adopted requirements consistent with 42 C.F.R. Part 50, Subpart F. It applies regardless of whether the Investigator is a direct employee of NYSBC or a subrecipient, contractor, or collaborator performing work under an NYSBC award.

3. Definitions

3.1 Investigator

The Principal Investigator and any other person at NYSBC—or at a subrecipient or contractor—who is responsible for the design, conduct, or reporting of research funded by the PHS or other covered federal agency, regardless of title or position. Co-investigators, key personnel, and senior personnel named in a grant application or award are presumptively Investigators under this Policy.

3.2 Institutional Responsibilities

An Investigator's professional responsibilities on behalf of NYSBC, including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data Safety Monitoring Boards.

3.3 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 and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity: a remuneration received from the entity in the twelve months preceding the disclosure that, when aggregated, exceeds
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\$5,000; or any equity interest in the entity that, when aggregated, exceeds \$5,000 in value or represents more than a 5% ownership interest.

- With regard to any non-publicly traded entity: a remuneration received in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000, or any equity interest (including stock, stock options, or other ownership interests).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related thereto, that exceeds \$5,000 in the twelve months preceding the disclosure.
- Reimbursed or sponsored travel (i.e., travel paid on behalf of the Investigator and not reimbursed by NYSBC) related to Institutional Responsibilities, regardless of value. This does not include travel that is paid from an NYSBC grant, contract, or sponsored account, nor travel funded directly by NYSBC.

The following are NOT considered Significant Financial Interests for purposes of this Policy:

- Salary, royalties, or other remuneration paid by NYSBC to the Investigator.
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education (as defined in 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.
- Income from service on advisory committees or review panels for 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.

3.4 Financial Conflict of Interest (FCOI)

A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research, as determined by NYSBC following review under this Policy.

3.5 FCOI Officer

The individual designated by NYSBC to receive SFI disclosures, conduct FCOI reviews, manage FCOI proceedings, and fulfill reporting obligations to the NIH and other federal agencies. The FCOI Officer is currently the Managing Director. In the event of a conflict involving the FCOI Officer, the matter shall be referred to the Executive Director or, where the Executive Director is implicated, to the Executive Committee of the Board.

3.6 Subrecipient / Contractor

Any entity performing a substantive portion of NYSBC's federally funded research under a subaward, subcontract, or other contractual arrangement.

4. Training Requirements

Before engaging in research related to any PHS-funded grant or award, and at least once every four (4) years thereafter, each Investigator must complete FCOI training as required

by 42 C.F.R. § 50.604(b). NYSBC designates the NIH's web-based Financial Conflict of Interest training module as its required training.

Investigators must also complete training immediately in the following circumstances:

- NYSBC's FCOI Policy is revised in a manner that materially alters Investigators' obligations;
- An Investigator is found to have been non-compliant with this Policy or an FCOI management plan; or
- An Investigator who is new to NYSBC and has not previously completed compliant training.

Certificates of training completion shall be maintained by the FCOI Officer and retained for at least three (3) years following the end of the award to which they relate.

5. Disclosure of Significant Financial Interests

5.1 Timing of Disclosure

Each Investigator must disclose all Significant Financial Interests (and those of the Investigator's spouse and dependent children) that are related to the Investigator's Institutional Responsibilities. Disclosures are required:

- No later than at the time of application for PHS-funded research;
- At least annually during the period of the award (NYSBC will conduct an annual disclosure update process each calendar year); and
- Within thirty (30) days of discovering or acquiring a new Significant Financial Interest (e.g., through purchase, marriage, inheritance, or a new consulting engagement).

5.2 Disclosure Obligation

Investigators must disclose all SFIs meeting the criteria in Section 3.3, even if the Investigator does not believe a conflict exists. It is the responsibility of the FCOI Officer—not the Investigator—to determine whether a disclosed SFI constitutes an FCOI. Investigators may not self-select what to disclose.

5.3 Procedure

Disclosures must be submitted using NYSBC's Financial Interests Disclosure Form, available from the FCOI Officer. Completed forms should be submitted to the FCOI Officer. Disclosures will be held in confidence consistent with Section 11 of this Policy.

6. Review of Disclosures

The FCOI Officer will review each disclosure within sixty (60) days of receipt to determine whether a disclosed SFI constitutes an FCOI—that is, whether the interest could directly and significantly affect the design, conduct, or reporting of the funded research.

In conducting this review, the FCOI Officer will consider:

- The nature of the financial interest and its relationship to the research;
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- The stage of the research;
 - The degree to which the Investigator controls or influences research outcomes, resource allocation, or data interpretation; and
 - Whether the interest is in an entity whose financial interests could be affected by the research.

The FCOI Officer will document the determination and rationale. If the FCOI Officer determines that an FCOI exists, the matter will be referred to the Executive Director for management and resolution prior to the expenditure of any federal funds. If the disclosure involves the FCOI Officer, review shall be conducted by the Executive Director. If the disclosure involves the Executive Director, review shall be conducted by the Executive Committee of the Board.

7. Management and Resolution of FCOIs

When an FCOI is identified, NYSBC will implement a written FCOI Management Plan that specifies the actions NYSBC has taken or will take to manage the conflict. The Management Plan shall be implemented prior to the expenditure of any PHS funds under the award, or as soon as practicable after identification of a newly discovered FCOI.

Management measures may include, individually or in combination:

- Public disclosure of the FCOI in publications, presentations, or other research communications;
- Appointment of an independent monitor to oversee the relevant portion of the research;
- Modification of the research plan;
- Disqualification of the Investigator from participation in the portion of the research that could be affected by the FCOI;
- Divestiture of the financial interest;
- Severance of the relationship that creates the conflict; or
- Such other conditions, limitations, or actions as the Executive Director deems appropriate.

If the Executive Director, in consultation with the FCOI Officer and other relevant parties, determines that imposing conditions or restrictions on the research would be either ineffective or inequitable, and that the potential negative impacts of the FCOI are outweighed by interests of scientific progress, technology transfer, or public health and welfare, the Executive Director may allow the research to proceed without such conditions and will document the rationale for that determination.

8. Retrospective Review and Mitigation

If NYSBC determines that an FCOI was not identified or managed in a timely manner—including when an Investigator fails to disclose an SFI, fails to disclose a new SFI in a timely manner, or does not comply with an FCOI Management Plan—NYSBC will conduct a retrospective review within one hundred twenty (120) days of learning of the non-

compliance to determine whether any PHS-funded research conducted during the period of non-compliance was biased in its design, conduct, or reporting.

NYSBC will document the retrospective review, including:

- The name of the Investigator;
- The name of the federal agency and grant number;
- The nature of the project;
- The nature, value, and timeframe of the SFI not disclosed or not managed;
- Whether the research was designed, conducted, or reported without bias; and
- The basis for the determination.

If the retrospective review concludes that bias may have occurred, NYSBC will promptly notify the NIH or applicable awarding agency and submit a Mitigation Report. The Mitigation Report will include the elements required by 42 C.F.R. § 50.605(a)(3) and will describe any corrective action taken or to be taken.

9. Reporting to Federal Agencies

NYSBC will provide FCOI reports to the NIH and applicable federal agencies as required by 42 C.F.R. Part 50, Subpart F, including:

- Prior to expending PHS funds under a new award, an FCOI report for any identified FCOI;
- Within sixty (60) days of identifying a new FCOI arising during an ongoing award;
- At the time a new Investigator joins a funded project and an FCOI is identified for that Investigator; and
- Annually thereafter for the duration of the project period.

FCOI reports will be submitted through the NIH eRA Commons FCOI Module or as otherwise required by the applicable agency.

10. Subrecipient and Contractor Requirements

NYSBC will include in each subaward or subcontract for federally funded research a requirement that the subrecipient or contractor comply with 42 C.F.R. Part 50, Subpart F. Each subaward or subcontract will specify:

- Whether the subrecipient will follow its own FCOI policy (if the subrecipient is another institution subject to PHS regulations) or NYSBC's Policy;
- The deadline by which the subrecipient must report identified FCOIs to NYSBC so that NYSBC can fulfill its reporting obligations; and
- The required submission of FCOI training certificates and completed Financial Interests Disclosure Forms to NYSBC's Administration Office at the time of award, annually during the award period, and within thirty (30) days of any change in FCOI status.

NYSBC will incorporate reported FCOI information from subrecipients into its own federal reporting obligations.

11. Confidentiality

SFI disclosures and FCOI determinations will be maintained in a careful and confidential manner. Access within NYSBC will be limited to those with an administrative need to review them, which will ordinarily include the FCOI Officer, the Executive Director, and, where the matter is escalated, the Executive Committee of the Board.

Nothing in this section limits NYSBC's obligations to report FCOI information to the NIH, other federal agencies, or the Department of Health and Human Services, or to make required disclosures publicly accessible as set forth in Section 12.

12. Public Accessibility

NYSBC's FCOI Policy will be posted on NYSBC's public website. Information concerning identified FCOIs held by the Principal Investigator and Senior/Key Personnel on PHS-funded projects will be made available to any member of the public upon written request, within five (5) business days of receipt of the request, in accordance with 42 C.F.R. § 50.605(a)(5).

At a minimum, the following information will be disclosed for each identified FCOI:

- The Investigator's name and title;
- The Investigator's role in the research;
- The name of the entity in which the SFI is held;
- The nature of the SFI (e.g., equity, consulting fees, sponsored travel); and
- The approximate dollar value of the SFI, using the ranges specified in 42 C.F.R. § 50.605(a)(5)(ii), or a statement that the value is not readily ascertainable.

This information will be updated at least annually and within sixty (60) days of identification of a new or revised FCOI. It will remain accessible for three (3) years from the date it was most recently updated.

13. Record Retention

The FCOI Officer will maintain all records relating to SFI disclosures, FCOI determinations, management plans, retrospective reviews, and federal reports for at least three (3) years following the later of: (a) the termination or completion of the award to which the records relate; or (b) the resolution of any federal action involving those records. Records will be made available to the NIH or HHS upon request.

14. Enforcement and Non-Compliance

Failure to comply with this Policy—including failure to disclose an SFI in a timely manner, failure to comply with an FCOI Management Plan, or providing false or incomplete information on a disclosure form—will be referred to the Executive Director for appropriate disciplinary or corrective action. Such action may include, without limitation, suspension from federally funded research activities, modification of research responsibilities, or termination of employment consistent with NYSBC's personnel policies.

If non-compliance has or may have biased the design, conduct, or reporting of federally funded research, NYSBC will promptly notify the applicable federal agency and undertake the retrospective review described in Section 8.

15. Administration and Policy Review

The FCOI Officer is responsible for day-to-day administration of this Policy, including receiving and reviewing disclosures, maintaining records, coordinating management plans, and ensuring timely federal reporting. The Executive Director retains final authority over FCOI management decisions.

This Policy will be reviewed at least every three (3) years and updated as necessary to reflect changes in federal regulations or NYSBC's organizational structure. The FCOI Officer is responsible for monitoring relevant regulatory developments and recommending revisions to the Executive Director and Board as appropriate.

16. Related Policies

This Policy should be read in conjunction with NYSBC's Policy on External Service, Consulting and Conflicts of Interest, which addresses consulting arrangements, time commitments, and broader conflict of interest principles applicable to NYSBC staff. In the event of any conflict between the two policies with respect to PHS-funded research, this Policy controls.

Approved April 21, 2026
