

## **The New York Society for the Prevention of Cruelty to Children FINANCIAL CONFLICTS OF INTEREST (FCOI) POLICY**

### **I. PURPOSE OF THIS POLICY**

The following represents the Financial Conflicts of Interest Policy (“Policy”) for The New York Society for the Prevention of Cruelty to Children (“The NYSPCC”). The Policy is intended to promote objectivity in Research (defined below) funded under Public Health Service (defined below) grants or cooperative agreements will be free from bias resulting from Investigator (defined below) Financial Conflicts of Interests (defined below). This Policy complies with Title 42, Part 50, Subpart F of the U.S. Code of Federal Regulations (“FCOI Regulation”).

### **II. APPLICABILITY**

This Policy applies to each Investigator at The NYSPCC who is planning to participate in or is participating in PHS Research funded by means of a grant or cooperative agreement. This Policy does not apply to Small Business Innovation Research Program Phase I applications.

### **III. DEFINITIONS**

- 1. FINANCIAL CONFLICT OF INTEREST (“FCOI”):** exists when the Society, through its designated official(s), reasonably determines that a Significant Financial Interest (defined below) could directly and significantly affect the design, conduct, or reporting of PHS-funded Research.
- 2. INVESTIGATOR:** a project director or principal Investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded Research or Research proposed for PHS funding, which may include collaborators and consultants.
- 3. FINANCIAL CONFLICT OVERSIGHT OFFICER (“FCCO”):** the individual who implements, oversees and enforces the FCOI policy.
- 4. INSTITUTIONAL RESPONSIBILITIES:** an Investigator’s professional responsibilities in connection with PHS-funded Research.
- 5. RESEARCH:** a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published

article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Component (defined below) through a grant or cooperative agreement, whether authorized under the Public Health Service Act (42 U.S.C. 201 et seq.) or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**6. PUBLIC HEALTH SERVICE (“PHS”):** an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which authority may be delegated.

**7. PHS AWARDING COMPONENT:** an organizational unit of the PHS that funds Research, such as the National Institutes of Health (“NIH”), the Centers for Disease Control and Prevention (“CDC”), the Health Resources and Services Administration (“HRSA”), the Substance Abuse and Mental Health Services Administration (“SAMHSA”), the Food and Drug Administration (“FDA”) and the Agency for Healthcare Research and Quality (“AHRQ”).

**8. SIGNIFICANT FINANCIAL INTEREST (“SFI”):**

(i) a financial interest consisting of one or more of the following interests of an Investigator, or the Investigator’s spouse or dependent children, that reasonably appears to be related to the Investigator’s Institutional Responsibilities:

- With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the Investigator’s disclosure of the interest and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. 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, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the Investigator’s disclosure of the interest, when aggregated, exceeds \$5,000, 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).

- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

**(ii)** 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 the Investigator's Institutional Responsibilities, except 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 need not be disclosed.

**(iii)** SFI does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by The NYSPCC to the Investigator if the Investigator is currently employed by The NYSPCC, including intellectual property rights assigned to The NYSPCC 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.
- 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.

## **IV. PROCEDURES**

### **A. Training**

1. The FCOO shall be responsible for ensuring that each Investigator is informed about the Policy, the FCOI Regulation and the Investigator's responsibilities under the Regulation and Policy.

2. The FCOO shall require each Investigator to complete training in the requirements of this Policy and the FCOI Regulation prior to engaging in Research related to any PHS-funded grant, cooperative agreement or contract and at least every four years. In addition, training shall be conducted immediately upon the occurrence of any of the following events:

- The revision of this Policy or The NYSPCC's procedure for implementing this Policy in a manner that affects the requirements of Investigators;
- The appointment of a new Investigator;
- The NYSPCC's determination that an Investigator has failed to comply with this Policy or a FCOI Management Plan (defined below).

3. A FCOI Disclosure Form shall be distributed to all Investigators during the required training under this Policy and prior to any participation in a PHS-funded project.

### **B. Disclosure, Review and Monitoring**

1. The FCOO shall review completed FCOI Disclosure Forms from Investigators planning to participate in or participating in PHS-funded Research. Investigators must submit FCOI Disclosure Forms:

- Prior to applying for PHS-funded Research;
- Within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI; and
- At least annually, in accordance with the specific time period prescribed by The NYSPCC, during the period of any PHS award.

2. An FCOI Disclosure Form shall list all of the Investigator's SFIs that reasonably appear to be related to the Investigator's Institutional Responsibilities. An FCOI Disclosure Form submitted in connection with an annual update must include any information that was not disclosed initially to The NYSPCC or on a subsequent FCOI Disclosure Form and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

### **C. Management of Financial Conflicts of Interest**

1. The FCOO shall review the FCOI Disclosure Forms submitted by each Investigator planning to participate or participating in PHS-funded Research activities prior to the expenditure of funds.

2. The FCOO will determine whether an Investigator's SFI is related to the specific PHS-funded Research project and, if so related, whether the SFI is an FCOI. In the event the FCOO is an Investigator subject to this Policy, his/her FCOI Disclosure Forms will be referred to The NYSPCC Executive Director. The NYSPCC will consider an Investigator's SFI related to PHS-funded Research when the FCOO reasonably determines that the SFI could be affected by the PHS-funded Research or is in an entity whose financial interest could be affected by the PHS-funded Research. The NYSPCC will find that an FCOI exists when the FCOO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research.

3. If an SFI is determined to be an FCOI, the FCOO will develop and implement a FCOI Management Plan which shall include, without limitation, the following:

- The role and principal duties of the conflicted Investigator in the Research project;
- The conditions or restrictions of the FCOI Management Plan;
- How the FCOI 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.

The conditions or restrictions of the FCOI Management Plan may include,

but are not limited to:

- Public disclosure of the FCOI (e.g., when presenting or publishing the Research);
- For Research projects involving human subjects Research, disclosure of 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 the FCOI;
- Modification of the Research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the Research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts

4. Whenever, in the course of an ongoing PHS-funded Research project, an Investigator who is new to participating in the Research discloses an SFI or an existing Investigator discloses a new SFI to The NYSPCC, the FCOO shall, within 60 days, review the SFI, determine whether it is related to PHS-funded Research in accordance with this Policy, determine whether it presents a FCOI in accordance with this Policy, and, if so, implement, on at least an interim basis, a FCOI Management Plan that shall specify the actions that have been and will be taken to manage such FCOI.

5. The FCOO will monitor Investigator compliance with FCOI Management Plans on an ongoing basis until the completion of the PHS-funded Research project.

#### **D. Reporting of a Financial Conflict of Interest to PHS**

1. The FCOO must submit to the applicable PHS Awarding Component a report regarding each FCOI ("FCOI Report") in accordance with this Policy and the FCOI Regulation. Each FCOI Report shall include sufficient information to enable the PHS to understand the nature and extent of the FCOI and assess the appropriateness of the FCOI Management Plan. Prior to expenditure of funds under a PHS-funded grant or cooperative agreement, the FCOO will submit an FCOI Report for every known FCOI. FCOI Reports regarding FCOIs disclosed by an Investigator who is participating in an existing project shall be submitted within sixty (60) days of the Investigator's disclosure of the FICO. At least annually,

the FCOO will provide the status of the FCOI and any changes to the Management Plan, if applicable, until the completion of the project. If the FCOO is also an Investigator on a PHS-funded Research project which includes an FCOI, then the FCOO will review the related FCOI Report.

2. All FCOI Reports must include sufficient information to enable the PHS to understand the nature and extent of the FCOI and to assess the appropriateness of the associated Management Plan. The FCOI Report must include, but may not be limited to:

- Project number or equivalent;
- The Principal Investigator or Contact Principal Investigator if a multiple Principal Investigator model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000 - \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- description of how the financial interest relates to the PHS-funded Research and why The NYSPCC determined that the financial interest conflicts with such Research; and
- description of the key elements of the management plan

#### **E. Enforcement Mechanisms, Remedies and Non- Compliance**

1. Instances of non-compliance include the following:

- Failure by an Investigator to disclose an SFI that is determined by The NYSPCC to constitute an FCOI;
- Failure by The NYSPCC to review or manage an FCOI; or
- Failure by the Investigator to comply with this Policy or a FCOI Management Plan.

2. The following process for reporting non-compliance must be followed:

- For any SFI which is identified as an FCOI subsequent to

The NYSPCC's initial FCOI Report to the PHS Awarding Component, an FCOI report shall be prepared and submitted by the FCOO within sixty (60) days of the identification of the non-compliance.

- In addition, The NYSPCC shall, within one hundred twenty (120) days of The NYSPCC's determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded Research project and determine whether any PHS-funded Research conducted during the period of non-compliance was biased in design, conduct or reporting. The NYSPCC will document the retrospective review. Such documentation shall include, without limitation, the following key elements:
  - Project number;
  - Project title;
  - PD/PI or contact PD/PI (if a multiple PD/PI model);
  - Name of the Investigator with the FCOI;
  - Name of the entity with which the Investigator has a financial conflict of interest
  - 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, The NYSPCC shall update the previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, The NYSPCC shall notify the PHS Awarding Component promptly and submit a mitigation report. The mitigation report must include, at a minimum:

- Key elements documented in the retrospective review;
- Description of the impact of the bias on the Research project; and
- The NYSPCC'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 of whether the Research project is salvageable).

Thereafter, The NYSPCC shall submit FCOI Reports annually in accordance with this Policy.

3. Upon being notified by The NYSPCC that the failure of an Investigator to comply with this Policy or FCOI Management Plan appears to have biased the design, conduct or reporting of the PHS-funded Research, the PHS Awarding Component may take appropriate action or refer the matter to The NYSPCC for further action. In addition, the PHS Awarding Component may, at any time, inquire about any Investigator's SFI regardless of whether such SFI resulted in The NYSPCC's determination of a FCOI. The NYSPCC shall permit on site review of all records of FCOIs. On the basis of a review of The NYSPCC's records, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded Research to such an extent that further corrective action is needed or that The NYSPCC has not managed the FCOI in accordance with the FCOI Regulation. In this case, the PHS Awarding Component may impose special award conditions, suspend funding or impose other enforcement mechanisms.

## **F. Responsibilities of Subrecipients**

1. If The NYSPCC carries out PHS-funded Research through a subrecipient, The NYSPCC must take reasonable steps to ensure that all subrecipient Investigators comply with the FCOI Regulation, including:
  - Mandating in The NYSPCC's written agreement with the subrecipient that the subrecipient will comply with its own FCOI policy and that the subrecipient's FCOI Policy complies with the FCOI Regulation;
  - Mandating in The NYSPCC's written agreement with the subrecipient, in the event the subrecipient will comply with its own FCOI policy, that the subrecipient will timely disclose FCOI to The NYSPCC so that The NYSPCC may timely report such FCOI to PHS; and
  - Mandating in The NYSPCC's written agreement with the subrecipient that, if the subrecipient does not have its own FCOI policy that complies with the FCOI Regulation or chooses not to comply with its own FCOI policy, the subrecipient will comply with this Policy and, in accordance with this Policy, disclose SFI that are directly related to the subrecipient's work for The NYSPCC.
2. The NYSPCC shall provide FCOI Reports to the PHS Awarding Component regarding the FCOI of a subrecipient's Investigators prior to the expenditure of PHS funds and within sixty (60) days following any subsequent identification of FCOI.

## **G. Public Accessibility**

1. The NYSPCC shall make this Policy publicly available via a publicly accessible Web site prior to The NYSPCC's expenditure of any funds under a PHS-funded Research project.
2. The FCOO will, within five (5) business days, provide a written response to any request for information concerning any SFI disclosed to The NYSPCC that meets the following three criteria:
  - The SFI was disclosed and is still held by the Investigator;
  - The NYSPCC determines that the SFI is related to the PHS-funded Research; and

- The NYSPCC determines that the SFI is an FCOI.
3. The SFI information that The NYSPCC makes available via written response shall include the following:
- Project number or equivalent;
  - PD/PI or Contact PD/PI if a multiple PD/PI model is used;
  - Name of the Investigator with the FCOI and the Investigator's role and title;
  - Name of the entity with which the Investigator has an FCOI;
  - Nature of the SFI (e.g., equity, consulting fee, travel reimbursement, honorarium);
  - Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000 -\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
  - A note stating that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of The NYSPCC's identification of a new FCOI, which should be requested subsequently by the requestor.

#### **H. Maintenance of Records**

The FCOO shall maintain all PHS Financial Disclosure Forms and all related records of actions taken by The NYSPCC with respect to disclosures of financial interests for a period of three (3) years from the date of submission of the final expenditures report to PHS or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report.

Information concerning an Investigator's SFI must remain available for responses to written requests for at least three (3) years from the date that the information was most recently updated.

*Questions about this policy should be directed to Stephen P. Forrester, Financial Conflict Oversight Officer (FCOO), at: [sforrester@nyspcc.org](mailto:sforrester@nyspcc.org)*