

Financial Conflict of Interest Policy

Purpose

1. Advancing the research mission of the Florida Pediatric NCORP requires facilitating the translation of new discoveries into therapies that contribute to the larger society. Increasingly, collaboration with the private, for-profit sector plays an important role in this process. The participating hospitals of the Florida Pediatric NCORP encourage collaborative relationships with the private sector; however, the financial and other incentives that accompany such involvement may lead to Conflicts of Interest or Commitment (“Conflicts”) that may need to be reduced, managed or eliminated.
2. The purpose of this policy is to maintain best practices for ensuring objectivity in research and preserve the credibility of the Florida Pediatric NCORP and its participating researchers, faculty and professional staff through a transparent procedure for conflict disclosure and resolution. This policy is guided by federal regulatory requirements for the disclosure, review, management, and reporting of conflicts, mandated in the DHHS/PHS regulations 42 CFR Part 50.

Scope

This policy applies to all Florida Pediatric NCORP participants, including, researchers, faculty, and professional staff, who are involved in the design, conduct or reporting of research. Designated provisions of this policy apply to Investigators applying for or conducting research funded by federal agencies such as the Public Health Service (PHS), including the National Institute of Health (NIH), the National Cancer Institute (NCI), and the Food and Drug Administration (FDA), which are subject to agency-specific regulations relating to reporting Financial Interests and/or Financial Conflicts of Interest (non-PHS) in research.

Policy

1. Any form of remuneration received from or any Financial Interest an Investigator has in any Vendor shall be in strict accordance with this policy.
2. Investigators shall avoid activities that may create bias in research design, conduct or reporting.
3. Any activities that interfere with or dilute a primary commitment to the Florida Pediatric NCORP (a “Conflict of Commitment”) should be avoided.
4. Investigators must disclose their Significant Financial Interests (“SFIs”) and Extramural Activities that are reasonably related to their Institutional Responsibilities for the previous 12 months, as well as any estimated values for any Significant Financial Interest or Extramural Activity expected over the next 12 months must also be disclosed.
5. All Investigators must complete Financial Conflict of Interest (“FCOI”) training.

6. The Florida Pediatric NCORP shall report all FCOIs as required by the applicable funding agency.

Disclosure

- 1) Upon agreement with the Florida Pediatric NCORP to participate in research related activities, and annually thereafter, Investigators must disclose all SFIs and Extramural Activities that are reasonably related to their Institutional Responsibilities. Investigators must also disclose the SFIs of their Immediate Family and Household Members, when such interests relate to an Investigator's Institutional Responsibilities.
- 2) Investigators must update their Disclosure Forms within 30 days of receiving equity or remuneration for a new Extramural Activity or when they or their Immediate Family or Household Members acquire a new SFI related to an Investigator's Institutional Responsibilities.
- 3) Investigators planning to engage in research or consulting, are asked to update their Disclosure Forms when:
 - a. externally-funded research applications are submitted to industry supported studies.
 - b. research protocols are submitted to their onsite Institutional Review Board ("IRB").
 - c. consulting agreements are signed.
- 4) Investigators must disclose if they supervise any relative (individual related by blood, adoption or marriage) or household member.

Disclosure Review, Conflict Determination and Management Plans

- 1) Disclosure Forms must be provided to the Investigator's Department Chair or supervisor, and the Florida Pediatric NCORP Administrative Central Office. The department chairs and supervisors will assist the Administrator in determining whether any disclosed SFI relates to research and thus requires a FCOI evaluation.
- 2) As appropriate, the NCORP Principal Investigator and the NCORP Administrator shall review and determine if a COI or FCOI exists, and recommend a Management Plan.
- 3) If a FCOI exists, a Management Plan is required and will be approved by the NCORP PI and Administrator.
- 4) The Compliance Office at the participating hospital shall be notified of the approved management plan, as well as the Investigator and his/her Department Chair or supervisor of the Conflict determination and the recommended Management Plan.

5) If the Compliance Office, Department Chair or supervisor and/or the Investigator disagree with the FCOI decision or the recommended Management Plan, the issue will be referred to the participating hospitals COIC for review and final determination.

6) The onsite Compliance Office will then be responsible for monitoring compliance with all Management Plans.

Reconsideration Process

1) An Investigator may submit a written request for reconsideration to the onsite COIC and the NCORP Central Office after being notified of a Conflict determination and Management Plan.

2) After reconsideration, the onsite COIC's subsequent decision regarding the Conflict and any related Management Plan shall be final.

Reporting to External Funding Agencies

1) Initial FCOI (PHS) Report

a. New PHS-funded Research Projects – If a FCOI (PHS) exists, an initial FCOI report will be sent to PHS prior to the expenditure of funds. However, if a FCOI (PHS) is eliminated prior to the expenditure of funds, a report shall not be required.

b. Ongoing PHS-funded Research Projects - after making a FCOI determination, a report will be sent to PHS for any FCOI (PHS) identified subsequent to the initial FCOI report.

2) PHS Retrospective Review and Mitigation Reports

a. If an SFI was not disclosed or reviewed in a timely manner in an ongoing PHS-funded research project, the onsite Compliance Office will be asked to determine if the SFI relates to research and if a FCOI (PHS) exists.

b. If a FCOI (PHS) exists, the onsite Compliance Office shall be asked to implement an interim Management Plan, report to the NCORP Central Office and to PHS (within 120 days of discovery of noncompliance), and conduct and document a retrospective review of the Investigator's activities and the research to determine if there is any bias in research design, conduct or reporting.

c. If appropriate, an update to the previously submitted FCOI report shall be sent to PHS.

d. If bias is found, a mitigation report will be developed and PHS shall be notified promptly.

2) Annual FCOI Report

- a. For any previously reported FCOI (PHS), an annual FCOI report will be submitted to PHS for the duration of the PHS-funded research project.
- b. For any previously reported FCOI (non-PHS), FCOI or other reports will be submitted to the extent required by the applicable funding agency.

Confidentiality

- 1) All Disclosure Forms and their contents shall be treated as confidential and such information shall only be revealed as necessary to implement and enforce this policy or as required by applicable law.

Non-Compliance and Disciplinary Actions

- 1) Individuals subject to this policy are expected to comply fully and promptly.
- 2) Individuals who deliberately or repeatedly fail to fully and truthfully disclose Extramural Activities or Significant Financial Interests, or fail to comply with any Management Plan shall be subject to onsite institutional disciplinary actions.

Sponsored Research and Consulting

- 1) An Investigator is prohibited from serving as both a paid consultant to a company and as a recipient of sponsored research funds from the same company without approval of the NCORP PI, the NCORP Administrator, and the onsite Compliance Office.
- 2) Investigators are permitted to consult up to the equivalent of 24 working days per calendar year with for-profit entities.
- 3) There is no strict limit on consulting time Investigators may devote to non-profit or government entities.
- 4) The use of Florida Pediatric NCORP's name or participating hospitals facilities for personal benefit or non-hospital activities (e.g. consulting) is prohibited.

Sponsored Travel Disclosure Requirements

- 1) All Sponsored Travel must be disclosed to the NCORP Central Office prior to travel.
- 2) All Sponsored Travel shall be in strict accordance with Florida Pediatric NCORP policies, specifically, Vendor-sponsored travel is not permissible unless an exception is granted.

FCOI Training

- 1) All participating NCORP sites require their Investigators to train on this policy:
 - a) Upon hire and annually thereafter.
 - b) Prior to engagement in research.
 - c) Immediately if noncompliance is discovered or if policy revisions affect the requirements of those individuals subject to this policy.

Record Retention

- 1) The Florida Pediatric NCORP Central Office shall maintain all records relating to Conflict of Interest and Commitment disclosures for at least 3 years from the date of submission.

Public Accessibility

- 1) This policy shall be made available via **www.faptop.org**

References

42 CFR Part 50 and 45 CFR Part 94- Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought. Establishes standards to be followed by institutions that apply for or receive research funding from PHS Awarding Components.