

RESPIRATORY HEALTH ASSOCIATION FINANCIAL CONFLICT OF INTEREST POLICY

This Financial Conflict of Interest policy (the “**Policy**”) applies to all Public Health Service-sponsored Research of Respiratory Health Association (the “**Institution**”). The purpose of this Policy is to ensure that the design, conduct, and reporting of Research conducted by or on behalf of the Institution is free from bias resulting from a Financial Conflict of Interest. As discussed herein, the Institutional Official is responsible for ensuring implementation of this Policy and may suspend all relevant activities until the Financial Conflict of Interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of this Policy may also constitute cause for disciplinary or other administrative action pursuant to Institution policy.

This Policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize Financial Conflicts of Interest, and must respond appropriately when Financial Conflicts of Interest arise. To that end, this Policy informs Investigators about situations that generate Financial Conflicts of Interest related to Research and provides mechanisms for Investigators and the Institution to manage those Financial Conflicts of Interest that arise. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of Financial Conflicts of Interest arises, an Investigator should discuss the situation with the Institutional Official.

This Policy is drafted in accordance with the guidelines set forth in 42 C.F.R. § 50, Subpart F (the “**Regulations**”) and is intended to comply with all requirements of the Regulations. In the event of any apparent discrepancy between this Policy and the Regulations, the Regulations shall control.

DEFINITIONS

COI Committee means the individual or committee that advises the Institutional Official on Financial Conflict of Interest matters. A COI Committee may be established at the discretion of the Institutional Official, and the member(s) of the COI Committee may be appointed by the Institutional Official as necessary.

Family means any member of the Investigator’s immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

- a) If with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) If with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) If with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) Is income related to intellectual property rights and interests; or
- e) Is reimbursed or sponsored travel undertaken by the Investigator that is related to the Investigator’s institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available.

Significant Financial Interest does NOT include:

- a) Salary, royalties, or other remuneration from the Institution;
- b) Income from the authorship of academic or scholarly works;
- c) Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers;
- d) Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
- e) Travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Financial Conflict of Interest means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored Research.

Institutional Official means the individual within the Institution who is responsible for the solicitation and review of disclosures of Significant Financial Interests related to the Investigator’s Institutional Responsibilities. An Institutional Official shall be designated by the Institution upon the adoption of this Policy and may be changed at the discretion of the Institution.

Institutional Responsibilities means the Investigator’s professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS-sponsored Research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to 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).

FINANCIAL CONFLICTS OF INTEREST

I. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

All Investigators are required to disclose their Significant Financial Interests to the Institution prior to an application for PHS sponsorship and on an annual and ad hoc basis, as described below. Such disclosures shall be made through the completion and submission of the Financial Disclosure Form (attached as Exhibit 1). The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms. The COI Committee will assist with the review process at the request of the Institutional Official.

A. Pre-Application Disclosure

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, each Investigator must affirm the currency of the Investigator's most recent annual Financial Disclosure Form or submit to the Institutional Official an updated Financial Disclosure Form. The Institution will not submit a Research proposal unless the Investigator(s) who will be involved in the Research have submitted such ad hoc disclosures.

B. Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution on an annual basis. All Financial Disclosure Forms shall be submitted to the Institutional Official or designee by October 1 of each year. The filing of an annual Financial Disclosure Form is mandatory, even if the Investigator has no Significant Financial Interests to report and/or there have been no updates since the last Financial Disclosure Form filed by the Investigator.

C. Ad hoc Disclosures

In addition to the annual disclosure, the following situations require ad hoc disclosure be made through the submission of a Financial Disclosure Form:

1. All Investigators must disclose their Significant Financial Interests to the Institution within thirty (30) days of their initial appointment or employment.
2. All Investigators must disclose any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

D. Travel

Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities. A Financial Disclosure Form must be completed for each trip, within thirty (30) days of the travel. Such disclosure must include, at a minimum:

1. The purpose of the trip,
2. The identity of the sponsor/organizer,
3. The destination,
4. The duration, and,
5. The monetary value of the trip, if known.

The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to evaluate whether the travel constitutes a Financial Conflict of Interest with the Investigator's Research.

II. REVIEW AND DECISION BY THE INSTITUTIONAL OFFICIAL

If the Financial Disclosure Form reveals a Significant Financial Interest, it will be analyzed promptly by the Institutional Official. The Institutional Official may request that the COI Committee or other designee assist with this review.

First, the Institutional Official will determine whether the Significant Financial interest is related to PHS-funded Research. A Significant Financial interest is considered to be related to PHS-funded Research if:

- A. The Significant Financial Interest could be affected by the outcome of the PHS-funded Research; or
- B. The Significant Financial Interest is in an entity whose financial status could be affected by the outcome of the PHS-funded Research.

If the Significant Financial Interest is determined to be related to PHS-funded Research, the Institutional Official must then determine whether it constitutes a Financial Conflict of Interest. A Financial Conflict of Interest exists when the Institutional Official determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research.

III. MANAGING A FINANCIAL CONFLICT OF INTEREST

If a Financial Conflict of Interest exists, the Institutional Official must develop and implement a written Management Plan (attached as Exhibit 2) to manage the Financial Conflict of Interest. The written Management Plan may include any or all of the following conditions:

- A. Public disclosure of the Financial Conflict of Interest (i.e., when presenting or publishing the results of the Research);
- B. Disclosure of the Financial Conflict of Interest directly to Research participants (for Research involving human subjects);
- C. Appointment of an independent monitor to oversee the Research;
- D. Modification of the Research plan;
- E. Change of personnel or personnel responsibilities, including disqualification of personnel from participation in a portion of the Research;
- F. Reduction or elimination of the Significant Financial Interest;
- G. Severance of the relationship that creates the Significant Financial Interest; or
- H. Any other necessary conditions as determined by the Institutional Official.

The affected Investigator must formally agree to the proposed management strategies and sign the written Management Plan before any related PHS-sponsored Research goes forward.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the Research results, and to otherwise oversee compliance with the Management Plan.

IV. REPORTING OF FINANCIAL CONFLICTS OF INTEREST TO PHS

When a Financial Conflict of Interest is determined to exist, the Institutional Official shall file a Financial Conflict of Interest report (“**FCOI Report**”), as indicated below:

A. Initial Report

Prior to the expenditure of funds under a PHS-funded Research project, the Institution shall submit to PHS an FCOI Report regarding an Investigator’s Financial Conflict of Interest and the Management Plan adopted by the Institution in response. If the Financial Conflict of Interest is eliminated prior to the initial expenditure of funds, no FCOI Report need be filed for that Financial Conflict of Interest.

A Subrecipient of the Institution’s PHS funding (see Section VIII below) that is operating under its own conflict of interest policy must conduct its own conflict review and submit any required FCOI Reports to the Institution prior to the expenditure of any funds.

B. Active Research

When a new Financial Conflict of Interest is identified during the course of ongoing Research (i.e., due to the addition of a new Investigator who has a Financial Conflict of Interest or the acquisition of a new Financial Conflict of Interest by a current Investigator), the Institution shall submit to PHS an FCOI Report within sixty (60) days of the identification of the Financial Conflict of Interest.

Where a new Financial Conflict of Interest is identified by a Subrecipient during the course of ongoing Research, the Subrecipient shall submit its FCOI Report to the Institution within forty-five (45) days of the identification of the Financial Conflict of Interest. The Institution will review this FCOI Report and forward to PHS.

C. Contents of FCOI Report

An FCOI Report shall include sufficient information to enable PHS to understand the nature of the Financial Conflict of Interest and to assess the adequacy of the Institutional Official’s Management Plan. The FCOI Report template is attached as Exhibit 3.

D. Ongoing Obligation to Report

Once the Institution has identified a Financial Conflict of Interest and filed an FCOI Report, it shall provide to PHS an annual FCOI Report that addresses the status of the Financial Conflict of Interest for the duration of the PHS-funded Research project. The annual FCOI Report must specify how the Financial Conflict of Interest is being managed or explain why the Financial Conflict of Interest no longer exists.

V. INVESTIGATOR NON-COMPLIANCE

A. Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

An Institutional Official's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator, COI Committee and, where applicable, the IRB, and will notify the Investigator of the right to appeal the decision. The Institution will promptly notify the PHS Awarding Component of the action taken or to be taken.

If a Subrecipient decides to impose sanctions on one of its own Investigators, a notification of such action shall be made promptly to the Institution for reporting to PHS.

B. Retrospective Review

If the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a Management Plan for a Financial Conflict of Interest, the Institutional Official or the COI Committee will complete a retrospective review of the Investigator's activities and the PHS-sponsored Research project to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research.

Documentation of the retrospective review shall include:

1. The project number;
2. Project title;
3. PI name;
4. Name of Investigator with the Financial Conflict of Interest;
5. Name of the entity with which the Investigator has the Financial Conflict of Interest
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review; and
8. Findings and conclusions of the review.

The Institutional Official will update any FCOI Report previously submitted to PHS specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review shall be completed within one-hundred twenty (120) days of the discovery. If bias is found, the Institution will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify:

1. Elements documented in the retrospective review;
2. A description of the impact of the bias on the Research project; and
3. The plan of action to eliminate or mitigate the effect of the bias.

C. Clinical Trials

In the event that PHS determines that a PHS-funded project involving clinical Research was designed, conducted, or reported by an Investigator whose Financial Conflict of Interest was not managed or reported by the Institution, the Institution shall require the involved Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the Research and to request an addendum to previously published presentations.

VI. TRAINING

Each Investigator must complete training prior to engaging in Research funded by PHS. The training must address this Policy, Investigator's responsibilities regarding disclosure, and the PHS regulations. Investors must renew this training at least every four (4) years thereafter.

Additionally, an Investigator must immediately receive training in the event of any of the following:

- A. This Policy is substantively amended in a manner that affects the requirements of the Investigator;
- B. The Investigator is new to the Institution, or
- C. It is determined that the Investigator has not complied with this policy or with a Management Plan related to the Investigator's activities.

Subrecipient Investigators that have elected to comply with the Institution's Policy shall complete all necessary training in accordance with this Section VI.

VII. RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict Management Plans, and related documents for a period of three (3) years from the date the final expenditure report is submitted to the PHS. If any litigation, claim, financial management review, or audit is started before the expiration of the three (3) year period, the records shall be

retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

VIII. SUBRECIPIENTS

In the event that any portion of the Research will conducted by a Subrecipient of the Institution, the Subrecipient shall complete a Subrecipient Certification Form (attached as Exhibit 4). The Subrecipient shall elect in writing whether it will:

- A. Comply with this Policy; or
- B. Comply with the Subrecipient entity's conflict of interest policy.

If the Subrecipient elects to comply with its own conflict of interest policy, it shall certify to the Institution in writing that its conflict of interest policy complies with the Regulations. If the Subrecipient entity cannot provide such certification, it shall be required to comply with this Policy.

IX. CONFIDENTIALITY

To the extent permitted by law, all Financial Disclosure Forms, Management Plans, and related information will be confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding, or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide Financial Disclosure Forms, Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

X. PUBLIC ACCESSIBILITY

This Policy shall be published on the Institution's publicly-accessible website at the following web address: <http://www.lungchicago.org/research/>.

Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest disclosed to the Institution that meets the following criteria:

- A. The Significant Financial Interest was disclosed and is still held by the senior/key personnel;
- B. A determination has been made that the Significant Financial Interest is related to the PHS-funded Research; and
- C. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall include the following:

- A. The Investigator's name;
- B. The Investigator's title and role;
- C. The name of the entity in which the Significant Financial Interest is held;
- D. The nature of the Significant Financial Interest; and
- E. The approximate dollar value of the Significant Financial Interest or a statement that the value cannot readily be determined.

This information shall be updated at least annually, or within sixty (60) days as may be required by the Regulations.