

Financial Conflicts of Interest Policy for Public Health Service Funded Research: Policy 2.2.5

Section: Finance		Subject: Financial Conflicts of Interest – PHS Funded Research			
Controls Addressed:	Regulations	Controls			
	FCOI	42 CFR Part 50, Subpart F and 45 CFR 94			
Applies to: <input checked="" type="checkbox"/> LPHI <input checked="" type="checkbox"/> PATH <input checked="" type="checkbox"/> Business Partner		Effective from: 03/16/2026	Revised on:	Page 1 of 12	
Approved: 3/16/2026					

I. INTRODUCTION:

This policy governing financial conflicts of interest applies to all U.S. Public Health Service (PHS) sponsored research by the Louisiana Public Health Institute (LPHI). The LPHI Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflicts of interest (FCOI) are resolved or other action deemed appropriate by the LPHI Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to LPHI policy.

II. SCOPE

This policy applies to LPHI as the prime recipient or subrecipient of a PHS grant, and to executive leadership, and employees in positions that influence financial decisions, contracting, procurement, or regulatory compliance, including, but not limited to, Human Resources, Finance, Operations, Legal, and IT.

III. PURPOSE:

This policy applies to LPHI when serving as either a prime recipient or subrecipient of PHS-funded research, and to LPHI subrecipients involved in PHS-funded research under LPHI. This document sets forth LPHI’s policy on the disclosure, review, management, and resolution of FCOI, and pertains to Principal Investigators, Investigators, and employees in positions that could influence the design, conduct, or reporting of PHS-sponsored research, financial decisions, contracting, procurement, or regulatory compliance. For the purpose of this policy, Principal Investigators, Investigators, recipients, subrecipients, and employees in positions of influence are referred to as (“PI et al.”).

This policy is required by, and is intended to establish compliance with, the U.S. PHS National Institute of Health Regulation (42 CFR Part 50, Subpart F) “Promoting Objectivity in Research.” It is also intended to establish compliance with the National Science Foundation (NSF) and other granting agencies’ policies on conflicts of interest.

LPHI will inform the PI et al. of this policy regarding disclosure of SFIs, the applicable federal regulations at 42 CFR Part 50 Subpart F and 45 CFR Part 94, and will require compliance as a condition of participating in PHS-funded research.

IV. DEFINITIONS:

Clinical trial means any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices, or medical or other clinical procedures, such as surgery.

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse/domestic partner.

Financial conflicts of interest (FCOI) means a significant financial interest (or, where the LPHI Official requires disclosure of other financial interests) that the LPHI Official reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research.

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.

Financial interest does **NOT** include:

- a) salary, royalties, or other remuneration from the LPHI;
- 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 institutions affiliated with institutions of higher education, academic teaching hospitals, and medical centers;
or
- 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.

For PI et al., *financial interest* also includes any reimbursed or sponsored travel undertaken by the PI et al. and related to their LPHI responsibilities. This includes travel that is paid on behalf of the PI et al., as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state, or local governmental agencies, U.S. institutions of higher education,

research institutions affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research or proposals for such funding. Therefore, the regulations can apply to collaborators, consultants, postdoctoral fellows, graduate students, and others.

LPHI official means the individual within LPHI who is responsible for the solicitation and review of SFI disclosures, including those of the PI et al., and immediate family. For the purposes of this policy, the LPHI Official is designated as the CFO.

LPHI responsibilities means the Investigator's professional responsibilities associated with their LPHI appointment or position, such as research, teaching, clinical activities, administration, and LPHI internal and external professional committee service.

PI et al. means Principal Investigators, Investigators, recipients, subrecipients, and employees in positions of influence.

Prime recipient is the direct recipient of federal grant funds and is responsible to the granting agency for the project's overall conduct and fiscal accountability.

Public Health Service (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 general 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).

Research, Ethics, and HIPAA Compliance Committee (RECC) means the LPHI committee that advises the LPHI Official on conflicts of interest matters. The committee is comprised of the following: Admin, Data Analytics, Eval/Human Subjects Protection, PATH, Finance (CFO), HSR, Human Resources, IRB, Privacy Officer, Security Officer, and ITS.

Significant financial interest (SFI) means a financial interest that reasonably appears to be related to the PI et al. 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 exceeding \$5,000 related to intellectual property rights and interests not reimbursed through LPHI, or
- e) is reimbursed or sponsored travel related to their LPHI responsibilities.

Subrecipient receives a subaward from the prime recipient to carry out a substantive portion of the federal program and must adhere to most of the same federal requirements as the prime recipient.

V. CONFLICTS OF INTEREST:

This policy is predicated on the expectation that PI et al. should conduct their affairs to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this policy informs PI et al. about situations that generate conflicts of interest related to research, provides mechanisms for PI et al. and LPHI to manage those conflicts of interest that arise, and describes situations that are prohibited. Every PI et al. has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation that raises questions of conflict of interest arises, the PI et al. should discuss it with the LPHI Official.

VI. DISCLOSURE OF CONFLICTS OF INTEREST

All employees in positions that influence financial decisions, contracting, procurement, or regulatory compliance are required to disclose their outside financial interests as defined above to LPHI on an annual and ad hoc basis, as described below. The LPHI Official is responsible for the distribution, receipt, processing, review, and retention of disclosure forms. The RECC Committee may assist with the review of those forms and processes.

a) Annual Disclosures

All employees in positions that influence financial decisions, contracting, procurement, or regulatory compliance must disclose any SFI — including those of their spouse and/or dependent children — that relate to the PI et al. LPHI responsibilities. Disclosures must be submitted annually to the LPHI Official (or designee) by September 1 for the preceding fiscal year, or in accordance with funder requirements.

b) Ad Hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All

employees in positions that influence financial decisions, contracting, procurement, or regulatory compliance, must disclose their SFI to the LPHI Official within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the PI et al. has a SFI, the PI et al. must affirm the currency of the annual disclosure or submit to the LPHI Official an ad hoc updated disclosure of their SFI with the outside entity. LPHI will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all PI et al. must submit to the LPHI Official an ad hoc disclosure of any SFI they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the SFI.

c) Travel

PI et al. must also disclose reimbursed or sponsored travel related to their LPHI responsibilities, as defined above in the definition of financial interest and SFI. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The LPHI Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a FCOI with the Investigator's research.

VII. REVIEW AND DECISION OFFICIAL

If the disclosure form reveals a significant financial interest, it will be promptly reviewed by the LPHI Official to determine whether it constitutes an FCOI. If an FCOI exists, the LPHI Official will take action to manage the FCOI, including the reduction or elimination of the conflict, as appropriate. The LPHI Official may consult the RECC Committee for guidance in specific cases or in the application of the policy to particular situations.

A FCOI will exist when the LPHI Official determines that a SFI could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the LPHI Official determines that there is a FCOI that can be managed, they must develop and implement a written management plan. The affected PI et al. must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The LPHI Official will periodically review the ongoing activity and monitor the conduct of the activity to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

VIII. CLINICAL TRIALS

Review of SFI Related to Clinical Trials:

Clinical trials involve particularly sensitive issues when the PI et al. have a financial interest related to the clinical trial. In the event of non-compliance with reporting and/or management of a FCOI involving a PHS-sponsored clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this policy, the PI et al. must disclose the FCOI in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

IX. REPORTING TO PHS

The LPHI Official will report FCOI or non-compliance with PHS in accordance with PHS regulations. As a prime recipient, LPHI will report any FCOI to PHS related to any of the following events:

- Prior to the expenditure of funds;
- Within 60 days of identification for a PI et al. who is newly participating in the project;
- Within 60 days of any newly identified FCOI for existing PI et al. ;
- At least annually to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
- Following a retrospective review to update a previously submitted report

If the funding for the research is made available from a prime PHS awardee, LPHI will report to the prime awardee for any of the bullet points above.

All FCOI reported to PHS awarding components shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the FCOI and to assess the appropriateness of the LPHI's management plan. Elements of the FCOI report shall include no less than the following and may include such additional information that the LPHI Official of the PHS awarding component may request:

- Project Number;
- Principal Investigator;
- Name of the PI et al. with the FCOI;
- Name of the Entity with which the PI et al. has an FCOI;
- Nature of the Financial Interest (e.g. Compensation, Equity, Intellectual Property, consulting fees, Sponsored Travel, Reimbursed Travel);
- Value of the Financial Interest (dollar ranges are acceptable);
- Description of how the FCOI relates to the PHS-Funded Research and the basis for the Institution's determination that it is an FCOI; and
- Description of the key elements of the Institution's Management Plan, including:
 - Role and principal duties of the conflicted PI et al.;
 - Conditions of the Management Plan;

- How the Management Plan is designed to safeguard objectivity in the Research project;
- How the Management plan will be monitored to ensure PI et al. compliance; and
- Other information as needed, including information regarding the FCOIs of all subrecipient PI et al., consistent with the requirements of the 2011 PHS rule.

Additionally, LPHI will report to PHS as soon as reasonably possible any bias found within the design, conduct, or reporting of PHS-funded research. Such reporting will include all reporting elements, including a mitigation report, in accordance with federal regulations. LPHI will notify PHS promptly if an Investigator fails to comply with LPHI's FCOI Policy or if a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research.

X. INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of a PI et al. failure to comply with this policy, the LPHI Official may suspend all relevant activities or take other disciplinary action until the matter is resolved, or other action deemed appropriate by the LPHI Official is implemented.

The LPHI Official's decision to impose sanctions on a PI et al. because of failure to comply with this policy, or failure to comply with the decision of the LPHI Official, will be described in a written explanation of the decision to the PI et al., RECC Committee, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. LPHI will promptly notify the PHS awarding component of the action taken or to be taken. If funding for the research is provided by a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b) Retrospective Review

In addition, if the LPHI Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to a PI et al. failure to disclose a SFI that is determined to be a FCOI or failure by an PI et al. to materially comply with a management plan for a FCOI, a committee appointed by the LPHI Official will complete a retrospective review of the PI et al. 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 the project number, project title, name of individual(s) with the FCOI, name of the entity with which the individual(s) has the FCOI, reason(s) for the retrospective review, and detailed methodology used for the retrospective review, and findings and conclusions of the review.

The LPHI Official will update any previously submitted report to the PHS or the prime PHS awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. This retrospective review will be completed within 120 days of LPHI's determination of non-compliance for SFI not disclosed in a timely manner or previously reviewed, or whenever an FCOI is not identified or managed in a timely manner. 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 elements documented in the retrospective review, a description of the impact of the bias on the research project, and the plan of action to eliminate or mitigate the effect of the bias.

XI. SUBRECIPIENT REQUIREMENTS

With respect to awards to LPHI for PHS-Funded Research, each Institutional subrecipient shall:

- Provide written certification to LPHI that the subrecipient's FCOI policy complies with all applicable PHS and federal FCOI rules and requirements, or alternatively, and only if permitted by the institution, subrecipient researchers are subject to this LPHI policy with respect to disclosing SFI that are directly related to the subrecipient's work for LPHI;
- If the subrecipient's FCOI policy applies, specification of the time periods for the subrecipient to report all identified subrecipient research FCOI's to LPHI, which shall be sufficient to enable the LPHI to provide timely reports to PHS under this policy

XII. TRAINING

Each PI et al. must complete training on this policy, the responsibilities regarding disclosure, and the PHS regulations prior to engaging in research funded by PHS. PI et al. must also complete training within a reasonable period of time, as determined by the LPHI Official, in the event that this policy is substantively amended in a manner that affects the requirements of PI et al., if the PI et al. is new to LPHI, or if it is determined that the PI et al. has not complied with this policy or with a management plan related to their activities. Every four years, PI et al. must successfully complete a certified Conflicts of Interest for Public Health Service-funded research course.

XIII. RECORD RETENTION

The LPHI Official will retain all disclosure forms, conflict management plans, and related documents for a period of seven years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the seven year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

XIV. CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, LPHI may be required to make such information available to the PHS awarding component and/or HHS, to a requester concerning FCOI related to PHS funding or to the primary entity that made the funding available to LPHI, if requested or required. If LPHI is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the PI et al. will be informed of this disclosure.

XV. PUBLIC ACCESSIBILITY

LPHI will post this policy on its public website – www.lphi.org. Prior to the expenditure of funds, LPHI will ensure its process to respond to any requester within five business days of the request, including information concerning any SFI that meets the following criteria:

- a) The SFI was disclosed and is still held by the senior and key personnel;
- b) A determination has been made that the SFI is related to the PHS-funded research;
and
- c) A determination has been made that the SFI is a FCOI.

The information to be made available shall be consistent with the requirements of the PHS regulation.

XVI. REGULATORY AUTHORITY

This policy implements the requirements of 42 CFR 50 Subpart F and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

FINANCIAL CONFLICTS OF INTEREST DISCLOSURE

SECTION 1: Employee Information

- **Full Name:** _____
- **Job Title/Role:** _____
- **Email Address:** _____
- **Phone Number:** _____
- **Department:** _____
- **Project Title (if applicable):** _____
- **Project PI (if not self):** _____
- **Disclosure Type (check one):**
 - Annual Disclosure
 - Initial Disclosure (new employee or new project)
 - Ad Hoc Disclosure (new SFI or change in FCOI)
- **Are you involved in Public Health Service Funded Research?**
 - Yes No

SECTION 2: Significant Financial Interests (SFI)

In the past 12 months, did you or your spouse/domestic partner or dependent children have any of the following **related to your LPHI responsibilities**?

A. Compensation

- Any salary, consulting fees, honoraria, or other remunerations > \$5,000 from a publicly traded entity?
 - Yes NoIf yes, please describe:

- Any compensation > \$5,000 from a non-public traded entity?
 - Yes NoIf yes, please describe:

B. Equity Interests

- Equity (stock, stock options, ownership interest) in a publicly traded entity, where combined equity + compensation exceeds \$5,000?

Yes No

If yes, please describe:

- Any equity interest in non-publicly traded entity?

Yes No

If yes, please describe:

C. Intellectual Property Income

- Royalties or licensing income > \$5,000 not paid through LPHI?

Yes No

If yes, please describe:

D. Sponsored or Reimbursed Travel

- Have you participated in any sponsored or reimbursed travel in the past 12 months that was not funded by:

- a U.S. federal/state/local government,
- a U.S. higher education institution, or
- a U.S. academic teaching hospital or medical center?

Yes No

If yes, provide details:

- Sponsor/Organizers: _____
- Purpose of Travel: _____
- Destination: _____
- Duration: _____

- Estimated Value (if known): \$ _____

SECTION 3: Relatedness to LPHI Responsibilities

Do any of the interests disclosed above reasonably appear to be related to your LPHI responsibilities (i.e., your research, teaching, committee service, or administrative duties at LPHI)?

- Yes No

If yes, please describe:

SECTION 4: Certification

I hereby certify that:

- The information provided is accurate and complete to the best of my knowledge;
- I have read and understand LPHI’s Financial Conflict of Interest Policy;
- I agree to comply with any management plan that may be required to manage any identified conflict of interest.

Signature: _____ **Date:** _____

For LPHI Use Only

- **Date Reviewed:** _____
- **Reviewed by (LPHI Official):** _____
- **No FCOI Identified**
- **FCOI Identified – Management Plan Required**

Notes/Decision:
