

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.  
Commissioner



Dannel P. Malloy  
Governor  
Nancy Wyman  
Lt. Governor

<b>Policy Name:</b>	MANAGING FINANCIAL CONFLICTS OF INTEREST IN FEDERALLY FUNDED RESEARCH (DPH FCOI Policy)	<b>Number:</b>	LO-02-000
<b>Procedure:</b>	<a href="#">See Page 4</a>		
<b>Applies to:</b>	All DPH staff undertaking PHS-funded research in an investigator or key personnel capacity		
<b>Position Responsible:</b>	Chair, Human Investigations Committee		
<b>Effective Date:</b>	July 7, 2017	<b>Last Reviewed:</b>	June 29, 2017
<b>Approved</b>		<b>Date</b>	07/05/17

**PURPOSE:**

The federal government has issued regulations<sup>1,2</sup> requiring all institutions that apply for and receive US Department of Health and Human Services (DHHS) Public Health Service (PHS) **research funding** through contracts, grants and cooperative agreements to implement and maintain a written, enforced policy on conflict of interest in research that is in compliance with the regulations. This policy, together with the Financial Conflicts of Interest Disclosure Form (Appendix A), comprise DPH's policy on financial conflicts of interest.

This Policy promotes objectivity in research by establishing standards that preserve the integrity of research undertaken in the Department of Public Health (DPH) and ensure there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any conflicting financial interest of an investigator or key personnel.

DPH requires that all investigators and key personnel promptly and fully disclose, in writing (using the disclosure form, Appendix A), any significant financial interest (including those of a spouse or dependent child) that reasonably relates to their institutional responsibilities and, if applicable, comply with financial conflict of interest management or mitigation plans.

<sup>1</sup> [42 C.F.R. Part 50, Subpart F](#)

<sup>2</sup> [45 C.F.R. Part 94](#)



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## SCOPE:

This policy applies to all programs that apply for, or that receive, DHHS PHS funding through a contract, grant or cooperative agreement for the purposes of **research**, and to each investigator and key personnel who are participating in such research. For purposes of financial disclosure only, this regulation also covers the spouse and dependent children of the investigator and key personnel.

## DEFINITIONS:

Financial Conflict of Interest (FCOI) means a **significant financial interest** that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

FCOI Officer means the Institution's designated official responsible for oversight of the FCOI Policy and Procedures. The FCOI Officer shall be appointed by the Commissioner of DPH.

FCOI report means an Institution's report of a financial conflict of interest to an organization unit (component) of the PHS that funds the research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institution means any domestic or foreign, public or private, entity or organization that is applying for or that receives PHS research funding. Institution may refer to the **Connecticut Department of Public Health**.

Institutional Responsibilities means an investigator's or key personnel's professional responsibilities on behalf of the Institution which may include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Key personnel includes the PD/PI and any other personnel considered to be essential to work performance and identified as key personnel in the contract proposal, contract, grant application, progress report or other report submitted to the PHS by the Institution.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

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 involved may be delegated, including (but not limited to) the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control and Prevention, the Health Resources and Services Administration and the National Institutes of Health. A full list of PHS components can be found in Appendix B.

Research means a systematic investigation, study or experiment, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, 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). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Significant financial interest (SFI) means:

- (1) A financial interest consisting of one or more of the following interests of the investigator/key personnel (and those of their spouse and dependent children) that reasonably appears to be related to the investigator's or key personnel's institutional responsibilities:
  - (i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, 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;
  - (ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator/key personnel (or their spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (2) Investigators and key personnel must also disclose the occurrence of 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 their Institutional responsibilities. **Travel disclosure is not required if the travel 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.** The following details are required in the disclosure:
  - (i) Purpose of trip;
  - (ii) Name of sponsor/organizer;
  - (iii) Destination (city and state or country if outside the U.S.);
  - (iv) Duration of trip; and
  - (v) Total cost of trip including lodging; registration; fare for mode of travel (air, train, car, etc.); per diem and any other miscellaneous expenses.
- (3) The term significant financial interest **does not include:**
  - (i) Salary, royalties, or other remuneration paid by the Institution to the investigator/key personnel if the investigator/key personnel is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
  - (ii) Any ownership interest in the Institution held by the investigator/key personnel, if the Institution is a commercial or for-profit organization;

- (iii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator/key personnel does not directly control the investment decisions made in these vehicles;
- (iv) 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; or
- (v) 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.

## **POLICY AND PROCEDURES:**

### **1. DPH Responsibility**

- (i) DPH shall maintain an up-to-date, written, enforceable policy on financial conflicts of interest in accordance with federal regulations<sup>1,2</sup> and will make the policy and applicable federal regulations available on the DPH website.
- (ii) DPH will identify an official to seek and review disclosures of significant financial interest from each investigator/key personnel who is planning to participate in, or is participating in, PHS-funded research. This official will serve as the DPH FCOI Officer.
- (iii) DPH will inform each investigator/key personnel about the following:
  - a. Information about this policy and the corresponding federal regulations;
  - b. The responsibility of the investigator/key personnel to disclose any significant financial interest to the DPH FCOI Officer;
  - c. The requirement that the investigator/key personnel undertake mandatory FCOI training:
    - I. Prior to engaging in any PHS-funded research, and at least every 4 years thereafter;
    - II. Immediately when any of the following circumstances apply: (1) DPH revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators/key personnel; (2) an investigator/key personnel is a new DPH employee; or (3) the DPH FCOI Officer finds that an investigator/key personnel is not in compliance with the DPH FCOI policy or management plan.
- (iv) DPH will require that each investigator/key personnel who is planning to participate in the PHS-funded research disclose to the DPH FCOI Officer the investigator's/key personnel's significant financial interests (and those of their spouse and dependent children) no later than date of submission of the proposal or application for PHS-funded research.
- (v) DPH will require each investigator/key personnel who are participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, or as necessary throughout the period of the PHS-funded research project. Such disclosure shall include any information that was not disclosed initially or in a subsequent disclosure of significant financial interest (for example, any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated

information regarding any previously disclosed significant financial interest (for example, the updated value of a previously disclosed equity interest).

- (vi) DPH will require that each Investigator/key personnel who are participating in the PHS-funded research to submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (for example, through purchase, marriage, or inheritance) a new significant financial interest.
- (vii) If DPH subcontracts any elements of the PHS-funded research to an outside entity, DPH will take reasonable steps to ensure that each subrecipient investigator/key personnel shall be in compliance with this policy and federal regulations<sup>1,2</sup> by:
  - a. Incorporating as part of a written agreement with the subrecipient terms that establish whether the DPH FCOI Policy or that of the subrecipient will apply to the subrecipient's Investigators;
  - b. If the subrecipient's investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the written agreement referenced above that its policy complies with the DPH FCOI Policy and federal regulations.<sup>1,2</sup> If the subrecipient cannot provide such certification, the agreement shall state that subrecipient investigators are subject to the DPH FCOI Policy for FCOI training and for disclosing significant financial interests that are directly related to the subrecipient's work which they have been subcontracted by DPH to undertake;
  - c. If the subrecipient investigator must comply with the subrecipient's FCOI policy, the written agreement must specify that any FCOI disclosures reported to the subrecipient institution must be subsequently reported to the DPH FCOI Officer within 30 days.
  - d. DPH will report all subrecipient significant financial interest to the PHS prior to the expenditure of any funds and within 60 days of receiving subrecipient disclosure of significant financial interest.
- (viii) The DPH FCOI Officer will consult with the DPH Ethics Officer to determine whether an investigator's/key personnel's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest.
- (ix) DPH will take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report.
- (x) DPH will provide initial and ongoing FCOI reports to the PHS as described in section 5 below.
- (xi) All records relating to disclosures of financial interest, including any review and actions taken by DPH, will be maintained by the DPH FCOI Officer or designee for a period of three years from the date the final contract, grant or cooperative agreement expenditure report is submitted to the PHS.
- (xii) DPH shall certify in each proposal or application for PHS-funded research that it:
  - a. Has in effect a financial conflict of interest policy for all PHS-funded research activities;
  - b. Shall promote and enforce compliance with this policy;

- c. Shall manage financial conflicts of interest and provide initial and ongoing reports to the organizational unit of the PHS that funds the research;
- d. Agrees to make information promptly available to PHS relating to the disclosure and review of any financial conflict of interest; and
- e. Shall fully comply with federal regulations.<sup>1,2</sup>

## **2. Investigator and Key Personnel Responsibility**

- (i) Investigators must identify at the time of proposal submission and award setup, those project personnel, including subcontractors, outside collaborators and/or consultants, who meet the definition of investigators/key personnel. This information must be shared with the DPH FCOI Officer. In addition, investigators must identify any investigators, key personnel or subcontractors who join or leave the project during the course of the PHS-funded research study, and pass this information on to the DPH FCOI Officer.
- (ii) Investigators/key personnel must undertake mandatory FCOI training:
  - a. Prior to engaging in any PHS-funded research, and at least every 4 years thereafter;
  - b. Immediately when any of the following circumstances apply: (1) DPH revises its financial conflict of interest policy and procedures in any manner that affects the requirements of investigators/key personnel; (2) an investigator/key personnel is a new DPH employee; or (3) the DPH FCOI Officer finds that an investigator/key personnel is not in compliance with the DPH FCOI policy or management plan.
- (iii) Any DPH employee that serves as an investigator/key personnel and who is planning to participate in PHS-funded research must disclose to the DPH FCOI Officer any significant financial interest (and those of the investigator's/key personnel's spouse and dependent children) no later than the date of submission of the proposal or application for PHS-funded research, using the FCOI Disclosure Form provided by the DPH FCOI Officer (Appendix A).
- (iv) Investigators/key personnel who are currently participating in PHS-funded research must submit an updated disclosure of significant financial interests at least annually, or as necessary throughout the period of the PHS-funded research project. Such disclosure shall include any information that was not disclosed initially or in a subsequent disclosure of significant financial interest (for example, any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (for example, the updated value of a previously disclosed equity interest).
- (v) Investigators/key personnel who are currently participating in PHS-funded research must disclose using the FCOI Disclosure Form any new significant financial interest within 30 days of discovering or acquiring that significant financial interest.
- (vi) All investigators and key personnel have a duty to cooperate with DPH FCOI staff and to comply with DPH FCOI management plans and training requirements, in accordance with this policy.

## **3. Review of Disclosures by the DPH FCOI Officer**

- (i) Prior to the expenditure of any funds under a PHS-funded research project, the DPH FCOI Officer in consultation with the DPH Ethics Officer shall, consistent with federal regulations<sup>1,2</sup>:
  - a. review all investigator/key personnel disclosures of significant financial interests;

- b. determine whether any significant financial interests relate to PHS-funded research;
  - c. determine whether a financial conflict of interest exists; and
  - d. if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.
- (ii) A significant financial interest is related to PHS-funded research if the significant financial interest:
- a. could be affected by the PHS-funded research;
  - b. is in an entity whose financial interest could be affected by the research; or
  - c. could directly and significantly affect the design, conduct or reporting of the PHS-funded research.
- (iii) If the DPH FCOI Officer determines that a significant financial interest exists that is related to PHS-funded research, the Officer shall identify actions, if any, that must be taken by the investigator/key personnel to manage the financial conflict of interest.
- a. Actions to manage the financial conflict of interest may include but are not limited to:
    - I. Public disclosure of the financial conflict of interest when submitting articles for publication or presenting a paper about the research;
    - II. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
    - III. Appointment of an independent monitor that is capable of taking appropriate measures to protect the design, conduct and reporting of the research against bias resulting from the financial conflict of interest;
    - IV. Modification the research plan;
    - V. Change of staff or staff responsibilities, or disqualification of staff from participating in all or part of the research;
    - VI. Reduction or elimination of the financial interest; or
    - VII. Severance of relationships that create the financial conflict.
  - b. The actions required to manage the financial conflict of interest shall be identified in a management plan and compliance with the management plan shall be monitored by the DPH FCOI Officer on an ongoing basis until completion of the PHS-funded research project.
  - c. If the actions required to manage the conflict result in revisions to the research protocol or disclosing information to a research subject, investigators must submit revised material to the DPH Human Investigations Committee (and any other necessary IRBs) for review and approval.
- (iv) Whenever, in the course of an ongoing PHS-funded research project, an investigator/key personnel who is new to participating in the research project discloses a significant financial interest, or an existing investigator/key personnel discloses a new significant financial interest, the DPH FCOI Officer shall, within 60 days of receipt:
- a. review the disclosure report;

- b. determine whether an investigator's/key personnel's significant financial interest is related to PHS-funded research;
  - c. determine whether the significant financial interest is a financial conflict of interest; and
  - d. if so, implement on at least an interim basis a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.
- (v) Depending on the nature of the significant financial interest, the DPH FCOI Officer may determine that additional interim measures are necessary with regard to the investigator's/key personnel's participation in the PHS-funded research between the date of disclosure and the completion of the FCOI review
- (vi) Whenever the DPH FCOI Officer identifies a financial conflict of interest that was not disclosed in a timely manner, or was not previously reviewed by the Officer during an ongoing PHS-funded research project, the DPH FCOI Officer will, within 60 days:
  - a. review the significant financial interest;
  - b. determine whether it is related to PHS-funded research;
  - c. determine whether a financial conflict of interest exists; and
  - d. if so, Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.
- (vii) Whenever a financial conflict of interest is not identified or managed in a timely manner including (1) failure by the investigator/key personnel to disclose a significant financial interest that is determined by the DPH FCOI Officer to constitute a financial conflict of interest; (2) failure by DPH to review or manage such a financial conflict of interest; or (3) failure by the investigator/key personnel to comply with a financial conflict of interest management plan, the DPH FCOI Officer shall, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator's/key personnel's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- (viii) Such retrospective review will be documented and include the following elements:
  - a. Project number;
  - b. Project title;
  - c. Name(s) of project director or principal investigator;
  - d. Name of the investigator or key personnel with the FCOI;
  - e. Name of the entity with which the investigator or key personnel has a FCOI;
  - f. Reason(s) for the retrospective review;
  - g. Detailed methodology of the review process, composition of the review panel and the documents reviewed;
  - h. Findings of the review; and
  - i. Conclusions of the review.



- (ix) Based on the findings of the retrospective review, if appropriate, the DPH FCOI Officer shall update any previously submitted FCOI reports, specifying actions taken to manage the FCOI going forward.
- (x) If the retrospective review determines that the research was biased, the DPH FCOI Officer will promptly notify the PHS organizational unit that funds the research (awarding component) and submit a mitigation report. The mitigation report will include, but is not limited to, the following information:
  - a. All information described in section 3(viii) a-i above;
  - b. A description of the impact of the bias on the research project;
  - c. The DPH plan of action or actions taken to eliminate or mitigate the effects of the bias.
- (xi) Thereafter, the DPH will submit FCOI reports annually, as specified in section 5 of this policy.
- (xii) Whenever DPH implements a management plan, the DPH FCOI Officer shall monitor investigator/key personnel compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

#### **4. FCOI Training**

- (i) All DPH staff planning to undertake PHS-funded research must complete mandatory FCOI training:
  - a. prior to engaging in such research;
  - b. at least every 4 years thereafter until completion of the PHS-funded research; and
  - c. immediately when any of the following circumstances apply: (1) DPH revises its financial conflict of interest policy and procedures in any manner that affects the requirements of investigators/key personnel; (2) An investigator/key personnel is new to DPH; or (3) the DPH FCOI Officer finds that an investigator/key personnel is not in compliance with DPH FCOI policy or management plan.
- (ii) DPH mandatory FCOI training comprises:
  - a. Reading the DPH FCOI Policy in its entirety, signing the Declaration in Appendix C and providing a copy of the Declaration to the DPH FCOI Officer; and
  - b. Completion of the NIH FCOI tutorial and providing a copy of the Certificate of Completion to the DPH FCOI Officer.

The NIH FCOI tutorial is available here:

<https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> (Adobe Flash required)

<https://grants.nih.gov/grants/policy/coi/tutorial2011/Financial Conflict Of Interest - FCOI.pdf> (pdf format)

(Note: While the NIH tutorial is specific to 42 CFR 50 Subpart F, there is considerable overlap between this regulation and 45 CFR 94 and hence the tutorial is deemed to constitute appropriate training for investigators/key personnel undertaking research under PHS contract. Any questions should be directed to the DPH FCOI Officer.)

## 5. Reporting of FCOI Information to the PHS

- (i) Prior to the expenditure of any funds by DPH under a PHS-funded research project, the DPH shall provide to the PHS Awarding Component an FCOI report regarding any investigator's/key personnel's significant financial interest found by the DPH FCOI Officer to be conflicting and ensure that DPH has implemented a management plan in accordance with this policy. In cases in which the DPH FCOI Officer identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, DPH shall not be required to submit an FCOI report to the PHS Awarding Component.
- (ii) For any significant financial interest that the DPH FCOI Officer identifies as conflicting subsequent to DPH's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), DPH shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that a management plan has been implemented in accordance with this policy.
- (iii) Where a FCOI report involves a significant financial interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not reviewed or reported by a subrecipient in a timely manner), DPH also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, DPH is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- (iv) DPH shall provide to the PHS Awarding Component for any previously reported FCOI an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. DPH shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
- (v) FCOI reports shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of DPH's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:
  - a. Project/Contract number;
  - b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
  - c. Name of the Investigator/key personnel with the financial conflict of interest;
  - d. Name of the entity with which the Investigator/key personnel has a financial conflict of interest;
  - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
  - f. 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 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;

- g. A description of how the financial interest relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with such research; and
- h. A description of the key elements of DPH's management plan, including:
  - I. Role and principal duties of the conflicted investigator/key personnel in the research project;
  - II. Conditions of the management plan;
  - III. How the management plan is designed to safeguard objectivity in the research project;
  - IV. Confirmation of the investigator's/key personnel's agreement to the management plan;
  - V. How the management plan will be monitored to ensure investigator/key personnel compliance; and
  - VI. Other information as needed.

## **6. Public Accessibility to DPH FCOI Information**

- (i) DPH will post the DPH FCOI Policy on the DPH web site <http://www.ct.gov/dph>.
- (ii) Prior to the expenditure of any funds under a PHS-funded research project, DPH shall ensure public accessibility, via written response, to any requestor within 5 business days of a request, of information concerning any significant financial interest disclosed to the DPH FCOI Officer that meets the following three criteria:
  - a. The significant financial interest was disclosed and is still held by key personnel as defined in this policy;
  - b. The DPH FCOI Officer determines that the significant financial interest is related to the PHS-funded research; and
  - c. The DPH FCOI Officer determines that the significant financial interest is a financial conflict of interest.
- (iii) The information made available to the requestor shall include, at a minimum, the following:
  - a. The Investigator's name;
  - b. The Investigator's title and role with respect to the research project;
  - 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 (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.
  - f. A note 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 60 days of any new financial conflict of interest, which should be requested subsequently by the requestor.
- (iv) Information concerning the significant financial interests of an individual shall remain available, for responses to written requests for at least 3 years from the date that the information was most recently updated.

Appendix A: DPH Financial Conflicts of Interest Disclosure Form

Connecticut Department of Public Health Financial Conflict of Interest Disclosure Form

In accordance with the DPH policy *Managing Financial Conflicts of Interest in Federally Funded Research* (the DPH FCOI Policy), all investigators and key personnel undertaking PHS-funded research must disclose their personal significant financial interests (and those of their spouse and/or dependent children) related to their institutional responsibilities: (1) at the time of application for PHS-funded research; (2) with submission of their research proposal to the DPH Human Investigations Committee; or (3) within 10 days of discovering a significant financial interest.

Significant financial interests include:

- Remuneration received from a publicly traded entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000. For the purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary; equity interest includes stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
Remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000 or any equity interest in such entity.
Intellectual property rights and interests (e.g., patents, copyrights, trademarks) upon receipt of income related to such rights and interests.
All reimbursed or sponsored travel related to the individual’s institutional responsibilities which IS NOT reimbursed or sponsored by a federal, state or local government agency.

Section A

Name: Click here to enter text.

Telephone: Click here to enter text.

Email: Click here to enter text.

DPH section/program: Click here to enter text.

PHS-funded research project title: Click here to enter text.

PHS awarding component: Click here to enter text.

Use abbreviations in Appendix B

Funding start/end dates: Start: Click here to enter a date. End: Click here to enter a date.

Role in project: Click here to enter text.

Project PI (if not PI): Click here to enter text.

Do you, your spouse or dependent children have any significant financial interests related to your Institutional Responsibilities? [ ] Yes [ ] No

If Yes, complete Section B

Signed: \_\_\_\_\_

Date: Click here to enter a date.

# Connecticut Department of Public Health Financial Conflict of Interest Disclosure Form

## Section B

If you answered **Yes** in section A, please provide the following information for each significant financial interest.

<u>Name of entity:</u>	<u>Nature of financial interest:</u> <i>E.g., equity, consulting fee, honoraria, paid authorship, intellectual property rights</i>	<u>Monetary value of financial interest:</u> <i>Estimate the approximate value if the exact value is not readily available</i>
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- 1.
- 2.
- 3.

*Add/delete rows as necessary*

During the past 12 months did you receive a payment, either as an advance or a reimbursement, for travel (either transportation, lodging or meals) from a for-profit organization or a non-university non-profit organization, or were the costs of travel (alone or together with lodging and/or meals) paid directly for you by any such organization?

Yes       No

*Note: travel disclosure is not required if the travel is reimbursed by a federal, state or local government; institution of higher education; academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.*

Please provide the following information for each travel disclosure.

<u>Purpose of trip:</u>	<u>Sponsor/organizer:</u>	<u>Destination:</u>	<u>Duration of trip:</u>	<u>Monetary value of travel expenses:</u> <i>Estimate the approximate value if the exact value is not readily available</i>
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- 1.
- 2.
- 3.

*Add/delete rows as necessary*



## Appendix B: PHS Awarding Components

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- National Institutes of Health (NIH)\*

\*NIH comprises 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems (<http://www.nih.gov/icd>):

- National Cancer Institute (NCI)
- National Eye Institute (NEI)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of General Medical Sciences (NIGMS)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Nursing Research (NINR)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute on Drug Abuse (NIDA)

- National Institute on Minority Health and Health Disparities (NIMHD)
- National Library of Medicine (NLM)
- NIH Clinical Center (CC)
- Center for Information Technology (CIT)
- Center for Scientific Review (CSR)
- Fogarty International Center (FIC)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Complementary and Integrative Health (NCCIH)



## Appendix C: DPH FCOI Policy Declaration

Please review the DPH policy on Managing Financial Conflicts of Interest in Federally Funded Research (DPH FCOI Policy) and sign and date the declaration below to indicate that you understand your responsibilities as an investigator/key personnel in PHS-funded research.

I have read the DPH FCOI Policy and understand the definition of Significant Financial Interest (SFI) and how it applies to me and my family.

I will promptly and fully disclose any Significant Financial Interest (including those of a spouse or dependent child) that reasonably relate to my PHS-funded research at DPH and, if applicable, will comply with any financial conflict of interest management or mitigation plans

I will submit an FCOI Disclosure Form (Appendix A of the policy document) annually, and within 30 days of discovering or acquiring a new significant financial interest.

I will undertake DPH FCOI training:

- prior to engaging in PHS-funded research;
- at least every 4 years thereafter; and
- whenever directed to do so by the DPH FCOI Officer

Signed:	
Print name:	<a href="#">Click here to enter text.</a>
Job title:	<a href="#">Click here to enter text.</a>
Role in PHS-funded research:	<a href="#">Click here to enter text.</a>
Date:	<a href="#">Click here to enter a date.</a>