

**Policy and Procedure Manual
Administrative Manual
Administrative Institutional
Department: Compliance**



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**Public Health Service Financial
Conflicts of Interest:
Promoting Objectivity in
PHS-funded Research**

APPROVALS:

SLT: 10/13/20

Scope: X Medical Center X Beckman Research X Philanthropy X Foundation

I. PURPOSE / BACKGROUND

This policy codifies City of Hope’s standards and practices promoting objectivity in research projects funded by Public Health Service (PHS) grants. This policy reflects the standards for identifying, reviewing, managing, and eliminating Financial Conflicts of Interest established in the PHS Regulations title “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (42 C.F.R. Part 50, Subpart F) and “Responsible Prospective Contractors” (45 C.F.R. Part 94) (the “PHS Regulations”).

II. APPLICABILITY

This policy applies to City of Hope and its affiliates (“City of Hope”) and all City of Hope personnel who are Investigators as defined in Appendix One, and non-City of Hope sub-recipient Investigators who agree to abide by this policy pursuant to Section IV.D.2, in research funded by a PHS Awarding Agency as defined in Appendix One. For purposes of this policy, all references to “PHS” refer to the respective PHS Awarding Agency.

III. INFORMING AND TRAINING INVESTIGATORS

A. The Conflict of Interest and Commitment Committee (COICC) shall be responsible for ensuring that each Investigator is informed about (i) this policy, (ii) the responsibility of Investigators to disclose their Significant Financial Interests (SFI), as described below, and (iii) the PHS Regulations, by creating or approving a PHS Financial Conflict of Interest (FCOI) Training Program. The COICC shall require all Investigators who are City of Hope personnel, or who are non-City of Hope sub-recipient Investigators subject to City of Hope policies and procedures pursuant to Section IV.D.2, to complete training prior to engaging in PHS-funded research, and at least every four (4) years, and immediately when any of the following circumstances apply:

- 1) City of Hope revises its conflict of interest policies and procedures in any manner that affects the requirements of the Investigators;
- 2) A new Investigator who has not completed the required PHS FCOI Training Program in the last four (4) years is added as a participant to the an ongoing research project; or
- 3) City of Hope finds that an Investigator is not in compliance with the City of Hope’s conflict of interest policies and procedures or a management plan.

- B. All Investigators who fail to complete the required conflict of interest training in a timely manner will be prohibited from conducting PHS-funded research, and may be subject to disciplinary action.

IV. DISCLOSURE PROCESS

- A. All Investigators who are City of Hope personnel (including members of the Medical Staff and faculty and employees of the Beckman Research Institute) are deemed Covered Persons as defined in City of Hope's "Conflicts of Interest and Commitment: Disclosure, Identification and Approval" policy, and are required to complete or re-certify an Annual Disclosure via the electronic COI/C Disclosure System at least once every 12 months. The forms and questions that constitute the Annual Disclosure shall be reviewed by the COICC at least annually to confirm that they adequately solicit the disclosure of all Investigator SFIs as defined in this policy.
- B. The COI Manager (or Designee(s)) shall confirm that each Investigator listed on an application for PHS-funded research has completed an Annual Disclosure in the 12 months preceding the date of submission of the application.
- C. Whenever a new Investigator is added to an ongoing PHS-funded research project, the COI Manager (or Designee(s)) shall confirm that the Investigator has completed an Annual Disclosure in the 12 months preceding the date on which the Investigator intends to commence work on the PHS-funded research project. If the new Investigator has not previously been identified as a Covered Person as defined in the "Conflicts of Interest and Commitment: Disclosure, Identification and Approval" policy, the Investigator will immediately be deemed a Covered Person and will be required to complete an Annual Disclosure.
- D. Institutions that are sub-recipients, including subcontractors and consortium members, of PHS awards or contracts awarded to City of Hope must provide written assurances to City of Hope that will enable City of Hope to comply with the PHS Regulations. Specifically, City of Hope must enter into a written agreement with each sub-recipient establishing whether City of Hope's conflict of interest policies and procedures, including this policy, or those of the sub-recipient will apply to the sub-recipient's Investigators.
 - 1) If the sub-recipient's Investigators are to comply with the sub-recipient's policy, City of Hope shall require that the sub-recipient certify that its policy complies with the PHS Regulations. Additionally, the written agreement with the sub-recipient shall specify the time period(s) for the sub-recipient to report all FCOIs that have been identified by the sub-recipient to City of Hope.
 - 2) If the sub-recipient does not have a conflict of interest policy that is compliant with the PHS Regulations, City of Hope will require that the sub-recipient either adopt City of Hope's conflict of interest policies and procedures as the sub-recipient's own or shall require that the sub-recipient comply with City of Hope's policy.
 - i. If the sub-recipient is to comply with City of Hope's conflict of interest policies and procedures, the written agreement with the sub-recipient shall specify the time period(s) during which the sub-recipient's Investigators must submit an Annual Disclosure at least once every 12 months. The COI Manager (or Designee(s)) shall confirm that each sub-recipient Investigator subject to this subpart listed on an application for PHS-funded research has completed an Annual Disclosure in the 12 months preceding the date of submission of the application.

- E. All Investigators are required to update their Annual Disclosure record in the electronic COI/C Disclosure System or complete another COICC-approved disclosure update form within 30 days of discovering or acquiring a new SFI.
- F. Investigators may not undertake outside commitments without first submitting a disclosure form and obtaining prior written approval as outlined in Section II of City of Hope's "Conflicts of Interest and Commitment: Disclosure, Identification and Approval" policy.

V. REVIEWING SFIs AND DETERMINING THE EXISTENCE OF AN FCOI

- A. The COICC shall designate an Institutional Official(s) to review the Annual Disclosures solicited via the Disclosure Process described in Section V of Investigators planning to participate in, or participating in, PHS-funded research. In reviewing the Annual Disclosures, the Institutional Official(s) shall review each Investigator's disclosure of SFIs related to his or her Institutional Responsibilities.

The Institutional Official(s) shall determine that an FCOI exists where the Institutional Official reasonably determines that

- 1) An Investigator's SFI could be affected by the PHS-funded research project, or the SFI is with an entity whose financial interest could be affected by the PHS-funded research project

AND

- 2) The SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research project.

- B. Whenever PHS has awarded a new award or contract of funding of a PHS-funded research project, the Institutional Official(s) shall review each involved Investigator's SFIs and determine whether any FCOI exists prior to City of Hope's expenditure of funds under the new award or contract.
- C. Whenever a new Investigator has been added to an ongoing PHS-funded research project, the Institutional Official(s) shall review the Investigator's SFIs and determine whether any FCOI exists within 60 days of the new Investigator having been added to the research project.
- D. Whenever an Investigator working on an ongoing PHS-funded research project discloses a new SFI, the Institutional Official(s) shall review the Investigator's new SFI and determine whether any FCOI exists within 60 days of the new SFI having been disclosed.
- E. The Institutional Official(s) shall maintain a record of each review of an SFI and determination of whether an FCOI exists. This record shall include
 - 1) A description of the SFI, including the name of the entity in which the SFI is held, the type of the SFI, and the value of SFI,
 - 2) A description or copies of the documents regarding the PHS-funded research project that were reviewed (e.g., the study application, Specific Aims document, or a description of the research provided by the Investigator), and
 - 3) A clear statement of whether the Institutional Official(s) determined an FCOI exists.

The COICC shall review this record and confirm or disapprove the Institutional Official(s)'s findings at the COICC's monthly meetings, or as required in Section VI.

- F. The COICC may, at its discretion, directly review the SFIs of Investigators to determine whether FCOIs exist pursuant to the process described in this section.

VI. MANAGING FCOIs

- A. Whenever the COICC confirms the Institutional Official(s)'s finding of an FCOI or otherwise determines that a manageable FCOI exists, it shall implement management conditions, or condition an Investigator's involvement in a PHS-funded research project on the reduction or elimination of an SFI, by creating an appropriate FCOI management plan, which may include, but is not limited to, the following conditions:
 - 1) Public disclosure of FCOIs (e.g., when presenting or publishing the research);
 - 2) For research projects involving human subjects research, disclosure of FCOIs directly to participants;
 - 3) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
 - 4) Modification of the research plan;
 - 5) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - 6) Reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or
 - 7) Severance of relationships that create FCOIs.
- B. Whenever PHS has awarded a new award or contract funding a PHS-funded research project and an FCOI exists, the COICC shall implement an appropriate management plan, prior to the expenditure of any funds under the PHS-funded research project in question.
- C. Whenever a new Investigator who is determined to have an FCOI has been added to an ongoing PHS-funded research project, the COICC shall implement an appropriate management plan within 60 days of the new Investigator having been added to the ongoing research project.
- D. Whenever an Investigator working on an ongoing PHS-funded research project discloses a new SFI that is determined to constitute an FCOI, the COICC shall review the SFI and implement an appropriate management plan within 60 days of the new SFI having been disclosed.

VII. FCOI REPORTS

- A. Whenever the COICC determines that an FCOI exists, or confirms the Institutional Official(s)'s finding that an FCOI exists, prior to the expenditure of any funds under a PHS-funded grant or contract, City of Hope shall submit an FCOI Report to PHS via eRA Commons. The FCOI Report will include all information regarding the FCOI responsive to the current FCOI Report form screen in eRA Commons, including information identifying the PHS-funded research project, the Investigator, the entity in which the SFI is held, the nature of the SFI, a description of the COICC's or Institutional Official(s)'s finding of FCOI, and the actions taken to address the FCOI, including the FCOI management plan implemented by the COICC.
- B. For all previously submitted FCOI Reports, City of Hope shall provide PHS an annual FCOI report via eRA Commons that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI

report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. City of Hope shall provide annual FCOI reports to PHS for the duration of the project period (including extensions with or without funds) at the time the annual progress report or multi-year progress report, if applicable, is submitted, or at time of extension.

VIII. RETROSPECTIVE REVIEWS

- A. The COICC or its Designee shall conduct a retrospective review of an Investigator's activities and a given PHS-funded research project, or portion thereof, conducted during any period of noncompliance whenever one of the following noncompliance events occurs, within 120 days of learning of the noncompliance event:
- 1) An Investigator has not timely disclosed an SFI that is determined, under the process described in Section V, to be an FCOI;
 - 2) An Investigator has failed to comply with an FCOI management plan implemented by the COICC; or
 - 3) The Institutional Official(s) or COICC has failed to review or manage an SFI that is determined to be an FCOI, under the process described in Section V, within 60 days of the disclosure of the SFI or prior to the expenditure of PHS funds.
- B. Whenever an Investigator has not timely disclosed an SFI that is determined, under the process described in Section V, to be an FCOI or whenever the Institutional Official(s) or COICC has failed to review or manage an SFI that is determined to be an FCOI, under the process described in Section V, City of Hope shall, concurrent with its initiating a retrospective review, submit an FCOI report pursuant to section VII, and indicate on the FCOI Report that a failure to comply with the PHS regulations has occurred.
- C. The retrospective review shall include a review of the Investigator's activities and the PHS-funded research, or portion thereof, conducted during the time period of the noncompliance.
- D. The COICC or its Designee shall determine, in conducting its retrospective review, whether any PHS-funded research, or portion thereof, was biased in the design, conduct or reporting of such research.
- E. The COICC or its Designee, in conducting the retrospective review, shall document the retrospective review, and such documentation shall include:
- 1) Project number(s);
 - 2) Project title;
 - 3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - 4) Name of the Investigator with the FCOI;
 - 5) Name of the entity with which the Investigator has an FCOI;
 - 6) Reason(s) for the retrospective review;
 - 7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - 8) Findings of the review; and
 - 9) Conclusions of the review.
- F. If bias is found, City of Hope shall notify PHS promptly and submit a mitigation report via eRA Commons which shall include the elements documented in the retrospective review

pursuant to subsection E of this section, a description of any impact of the bias on the research, and City of Hope's plan to mitigate the effect of the bias.

IX. POLICY: MANDATORY DISCLOSURE OF AN FCOI IN PUBLIC PRESENTATIONS

In any case in which the United States Department of Health and Human Services or its delegate determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by City of Hope as required by the PHS Regulations, City of Hope shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

X. POLICY: PUBLIC AVAILABILITY OF CONFLICT OF INTEREST POLICIES AND FCOI REPORTS

- A. City of Hope shall make this policy publicly available via its website.
- B. City of Hope shall provide a written response within five (5) business days to any request for information concerning an SFI whenever
 - 1) The SFI was disclosed and is still held by an Investigator who is a senior/key personnel as defined in Appendix One;
 - 2) The COICC determined that the SFI is related to a PHS-funded research project; and
 - 3) The COICC determined that the SFI is an FCOI.
- C. City of Hope's written response to requests for information pursuant to subsection B of this section shall include the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI 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. The written response shall also 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 the City of Hope's identification of a new FCOI, which should be requested subsequently by the requestor.
- D. Information regarding the SFIs of Investigators shall remain available upon request for three (3) years from the date that the information was most recently updated.

Owner: Conflict of Interest Manager

Sponsor: Chief Ethics and Compliance Officer

Related Policies:

1. Conflict of Interest and Commitment: Establishment and Governance of the Conflict of Interest and Commitment Committee and General Compliance Principles
2. Conflicts of Interest and Commitment: Disclosure, Identification, and Approval
3. Continuing Medical Education (CME) Commercial Support Policy
4. Continuing Medical Education (CME) Conflicts of Interest
5. Industry Relationships – Authorship of Publications and Speaking Engagements
6. Institutional Conflict of Interest in Research

Appendix One – Acronyms, Terms and Definitions Applicable to this Policy

Appendix One
Acronyms, Terms and Definitions Applicable to this Policy

1. **Disclosure** – The disclosure of Financial Interests in non-City of Hope entities via the Annual Disclosure process completed and submitted via the electronic COI/C Disclosure System, or a research project-specific disclosure form, or any other form of disclosure approved by the Conflict of Interest and Commitment Committee (“COICC”).
2. **Financial Conflict of Interest (“FCOI”)** – A situation in which an Investigator holds a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
3. **FCOI report** – City of Hope’s report of an FCOI to PHS.
4. **Financial Interest** – Anything of monetary value, whether or not the value is readily ascertainable.
5. **Institutional Responsibilities** – An Investigator’s professional responsibilities on behalf of and to City of Hope, including clinical practice; research activities; teaching; and serving on City of Hope boards, panels, or committees.
6. **Investigator** – 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 any research funded by PHS at City of Hope, or proposed for such funding, and may include collaborators or consultants.
7. **Institutional Official** – Any COICC Designee appointed by the COICC to oversee, execute, or administer the provisions or requirements of this policy.
8. **Manage** – Taking action to address an FCOI, including reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
9. **Outside Commitment** – A compensated or uncompensated activity engaged in by a City of Hope employee or personnel with or on behalf of a non-City of Hope biomedical entity, or an activity with or on behalf of a non-City of Hope entity that involves the same skills and expertise required of the City of Hope employee or personnel to fulfill his or her professional obligations to City of Hope. Outside Commitments include consulting engagements, advisory board participations, speaking engagements, certain external conference or educational program participations, and service as an officer or board member of an external entity. Outside Commitments do not include those activities identified as Exempted Activities in Section II.D. of City of Hope’s “Conflict of Interest and Commitment: Disclosure, Identification, and Approval” policy.
10. **PHS Awarding Agency** – The organizational unit of 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 the National Institutes of Health, that funds a given research project that is subject to the PHS Regulations.
11. **Research** – A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses clinical, basic, and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS Awarding Agency through a grant, contract, or cooperative agreement.
12. **Senior/key personnel** – The project director, principal investigator, and any other person identified as senior/key personnel by City of Hope in the grant application, progress report, or any other report submitted to the PHS by the City of Hope in connection with a research project covered by this policy.
13. **Significant Financial Interest (“SFI”)** –
 - (1) A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s Institutional Responsibilities:
 - (i) Regarding publicly traded entities: Compensation received, in the 12 months preceding the date of disclosure, or equity held on the date of disclosure, whenever any such compensation and equity is valued at \$5,000 or greater when aggregated. Compensation 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) Regarding non-publicly traded entities: Compensation received, in the 12 months preceding the date of disclosure, when any such compensation is valued at \$5,000 or greater when aggregated or any equity interest held on the date of disclosure.

- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income of \$5,000 or more in the 12 months preceding the date of disclosure related to such rights and interests, except when the rights to such intellectual property are held by City of Hope, including when the Investigator receives a share of royalties from such intellectual property from City of Hope.
 - (iv) Any reimbursed or sponsored travel received in the 12 months preceding the date of disclosure valued at \$5,000 or more, with such value based only on the actual or reasonable estimated value of travel costs and not subject to aggregation with the value of any other Financial Interest related to an Investigator's Institutional Responsibilities. Travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education shall not constitute an SFI.
 - (v) Regarding foreign financial interests: Investigators, including subrecipient investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).
- (2) The following types of Financial Interests shall not constitute SFIs: salary, royalties, or other remuneration paid by City of Hope to a City of Hope Investigator; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency in the U.S., an Institution of higher education as defined at 20 U.S.C. 1001(a) in the U.S., an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education in the U.S.; or income from service on advisory committees or review panels for a Federal, state, or local government agency in the U.S., an institution of higher education as defined at 20 U.S.C. 1001(a) in the U.S., an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education in the U.S.