



CLINICAL RESEARCH CENTER FINANCIAL CONFLICT OF INTEREST POLICY: PROMOTING OBJECTIVITY IN RESEARCH

DEFINITIONS

Disclosure of significant financial interests: an Investigator's disclosure of significant financial interests to an Institution.

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

FCOI report: an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest: anything of monetary value, whether or not the value is readily ascertainable.

HHS: the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution: any domestic or foreign, public or private, entity or organization that is applying for, or that receives, PHS research funding. For the purposes of this policy, the Institution is Englewood Hospital and Medical Center.

Institutional responsibilities: an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as 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: 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.

Manage: 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.

PD/PI: a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

PHS: 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 (NIH).

Published regulations: the federal regulations applicable to this policy are found at 21 CFR 50 Subpart F.

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 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 subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel: the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

Significant financial interest (SFI): 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:

(1) Remuneration/Equity Interest

(a) *Publicly traded entity* - an SFI 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;

(b) *Non-publicly traded entity* - an SFI 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 (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(2) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(3) 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; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

Exclusions:

(a) salary, royalties, or other remuneration paid by EHMC to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution

(b) 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;

(c) income, reimbursement, or sponsored travel from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or

(d) income, reimbursement, or sponsored travel from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

POLICY STATEMENT

Englewood Hospital and Medical Center (EHMC) is committed to the principle that no proposed, awarded, or ongoing research project shall be biased by any significant financial interest of any investigator responsible for the design, conduct, or reporting of that research project. The purpose of this policy is to promote objectivity in research at EHMC. This policy applies to every EHMC Investigator (as defined above), who is planning to participate in or is participating in Public Health Service (PHS) funded research.

EHMC shall inform each investigator of this policy, the investigator's reporting responsibilities, and the federal regulations that bring about the policy. This policy will be made available on the www.EnglewoodHealth.org public website.

In each application for funding to PHS, EHMC will certify the following:

- (1) there is in effect at this institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which PHS-funding is sought;
- (2) the institution will report to the Sponsor the existence of any conflicting interest found by the institution, and assure that the interest has been managed, reduced or eliminated in accordance with federal regulations at the following time points: prior to the institution's expenditure of any funds, annually, and within sixty days of any new or newly discovered conflicts;
- (3) upon request, the institution agrees to make information available within five calendar days to the Public Health Service regarding all conflicting interests identified by the institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and
- (4) the institution will otherwise comply with the published regulations.

The President and Chief Executive Officer of EHMC, through this document, designates the Director of the Clinical Research Center (CRC) as the person to ensure the proper training of, and solicit financial disclosure statements from, each investigator who is planning to participate in PHS-funded research. The Director of the CRC will work with the EHMC Compliance Office to review the submitted forms, and oversee procedures to carry out the intent of this policy in accordance with the provisions specified in this document. The Director, in conjunction with the EHMC Compliance Office, may, at his or her discretion, ask other reviewers and advisors to review the financial disclosures required by this policy.

This policy requires that, by the time an application is submitted to PHS, each investigator who is planning to participate in the PHS-funded research has submitted to the CRC a statement indicating whether he or she has (or whether his/her spouse and dependent children have) any known Significant Financial Interests (SFI), as defined above, that reasonably appear to be related to the Investigator's institutional responsibilities. If an award is received for this proposed research, then the investigator(s) must update all financial disclosures on an annual basis during the period of the award and also within sixty days of the discovery of any new SFI.

The procedure will be put in motion at the time a proposal is receiving institutional review prior to official submission by EHMC to the Public Health Service (National Institutes of Health, Centers for Disease Control, etc.) or any other sponsor who requires compliance with regulations pertaining to objectivity in research. If there are no Significant Financial Interests to be disclosed, this is so noted in the proposal file. If there are Significant Financial Interests disclosed, the Director of the CRC will then commence initial review of the Significant Financial Disclosure Form.

RESPONSIBILITIES OF THE CLINICAL RESEARCH CENTER

The Director of the CRC shall:

- create an appropriate Significant Financial Disclosure Form and shall update or revise that form as required;
- ensure that all investigators receive Financial Conflict of Interest Training prior to submitting a proposal, and at least every four years thereafter;
- ensure that the requirements of this policy are communicated to investigators;
- receive and review, in conjunction with the EHMC Compliance Office, the Significant Financial Disclosure Form to determine whether the investigator has significant financial interests that could affect the design, conduct, or reporting of the research activities proposed for funding or funded by external agencies;
- take appropriate action to manage, reduce, or eliminate actual and potential conflicts of interest;
- certify, prior to the issuance of an award, to the awarding component of a federal agency the existence of significant financial interests and the plans of the institution for managing such interests;
- notify the awarding component of the federal agency of the identification and management, reduction, or elimination of any significant financial interests that originates or becomes known to EHMC after an award has been made;
- conduct and document retrospective reviews upon determination of noncompliance with this policy, including SFIs not properly disclosed or conflicts not properly managed;
- submit all required FCOI reports to the PHS funding agency within the allowable time frame;
- maintain confidentially, to the extent permitted by law, all disclosures and records of actions taken to manage significant financial interests for at least three years beyond the termination or completion of the

award or until resolution of any action by a federal agency involving the records, whichever is longer, and make these records available for audit by authorized agencies.

The President and CEO of EHMC may name another person to carry out these responsibilities if circumstances dictate.

RESPONSIBILITIES OF EHMC INVESTIGATORS

Each EHMC Investigator planning to participate in or participating in Public Health Service (PHS)-funded research must:

- identify on a Significant Financial Disclosure Form any SFI that reasonably appear to be related to his/her institutional responsibilities. A Significant Financial Disclosure Form covering significant financial interests of the investigator's immediate family must be submitted as well. The completed form and any necessary supporting documentation must be submitted to the Clinical Research Center at the following time points: (1) prior to official submission of the proposal, (2) annually, and (3) within thirty days of any new or newly discovered SFI;
- if a potential conflict is found, submit a Resolution Plan to the Compliance Office, and comply with all conditions and restrictions imposed by the Institution;
- take Financial Conflict of Interest training prior to official submission of the application, and then at least every 4 years thereafter.

EHMC does not expect that financial conflicts-of-interest will be an issue in most cases of proposals to external sponsors. Most information that is disclosed will not require any review past the initial stage. The information obtained will provide an opportunity for discussion, review, and appropriate management.

Noncompliance with this policy may result in sanctions.

INFORMATION TO BE DISCLOSED

Any 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 should be submitted on the EHMC Significant Financial Disclosure Form:

(1) Remuneration/Equity Interest

(a) *Publicly traded entity* - an SFI 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;

(b) *Non-publicly traded entity* - an SFI 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 (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);

(2) **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(3) **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 his/her institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Exclusions: this policy does not require disclosure of the following:

- (a) salary, royalties, or other remuneration paid by EHMC to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

- (b) 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;
- (c) income, reimbursement, or sponsored travel from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- (d) income, reimbursement, or sponsored travel from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

INITIAL REVIEW

The Director of the CRC shall conduct an initial review of all submitted financial disclosures. If this initial review determines that there is no conflict of interest, a note to that effect is signed and dated by the Director and placed in the proposal file in the CRC.

If, on the other hand, the initial determination is made that there may be a potential for conflict of interest covered by this policy, then it will be referred to the Compliance Office. The Administrative Liaison to the CRC may serve as an additional reviewer, as necessary.

Prior to review by the Compliance Office, the Investigator shall develop and present a Conflict of Interest Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a Significant Financial Interest. At a minimum the Resolution Plan shall address such issues as 1) public disclosure of significant financial interests; 2) review of research protocol by independent reviewers; and 3) monitoring of research by independent reviewers.

A conflict of interest exists when the Compliance Office, using the guidelines stated in this policy, *reasonably* determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The committee shall then recommend to the Administrative Liaison to the CRC the conditions or restrictions, if any, which should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests.

SUBSEQUENT REVIEW

The Administrative Liaison to the Clinical Research Center (Chief Population Health Officer) shall consider the recommendations made by the Compliance Office and decide whether to concur with those recommendations, modify them, or request additional review. The final decision as to whether EHMC perceives that a Conflict of Interest exists between the Investigator's Significant Financial Interests and the proposed research or sponsored project, and, the actions that will be taken will then be conveyed to the Principal Investigator (and any other key personnel) and the Director of the CRC.

ENFORCEMENT MECHANISMS

If it is determined that a conflict of interest exists (i.e., that a significant financial interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research) then conditions or restrictions will be imposed on the investigator(s) to manage, reduce, or eliminate such conflicts of interest. Examples of conditions or restrictions that might be imposed include, but are not limited to:

1. Public disclosure of significant financial interests;
2. Monitoring of research by independent reviewers;
3. Modification of the research plan;
4. Disqualification from participation in the portion of the research that would be affected by the significant financial interests;
5. Divestiture of significant financial interests; or
6. Severance of relationships that create conflicts.

If it is determined that a PHS-funded research project 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 a financial conflict of interest that was not disclosed or managed as required, EHMC will require the Investigator to:

- Disclose the conflict in each public presentation of the results, and
- Request an addendum to any previously-published presentations

OPPORTUNITIES FOR APPEAL

If any questions remain as to the resolution of the conflicts of interest and the institutional decision as stated by the Administrative Liaison to the CRC, the investigator(s) may appeal to the President and CEO for further consideration. The President may decide to let the decision stand or to convene a new *ad hoc* committee to review the appeal.

MAINTENANCE OF RECORDS

EHMC will maintain records of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any action involving these records, whichever is longer.

SUBRECIPIENT REQUIREMENTS

If EHMC carries out the PHS-funded research through subgrantees, contractors, or collaborators, EHMC will take reasonable steps to ensure that subrecipients comply with these regulations, either by complying with EHMC's policy or by providing assurances to EHMC that the subrecipient(s) also has policies that comply with these federal regulations.