Earlam College Financial Conflict of Interest Policy for Researchers Applying to or Holding Grants from the Public Health Service

The 2011 revised Federal regulation, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought (42 CFR Part 50, Subpart F), seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research performed under Public Health Service (PHS) grants (e.g., NIH, SAMHSA, or CDC grants) or cooperative agreements will be free from bias resulting from investigator financial conflict of interest. This regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation, or the “Final Rule.” (http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf). The regulation requires that financial conflicts of interest be appropriately managed and reported. The College therefore requires that Investigators disclose any Significant Financial Interest that would reasonably appear to be directly and significantly affected by an actual or potential conflict of interest in relationship with a sponsored project. This policy is intended to document that Earlham College, in applying for or receiving PHS funding from a grant or cooperative agreement, is in full compliance with all the regulatory requirements. Where there are substantive differences between this policy and the federal requirements, the requirements shall take precedence.

Fiduciary responsibility. Members of the Earlham College community serve the public trust and thus have a clear obligation to conduct the business of the College in a manner consistent with those responsibilities. All decisions of the board, officers of the College, faculty, and staff are to be made solely on the basis of a desire to promote the best interests of the College and the public good.

In the spirit of the public trust, faculty or staff proposing to receive funds from the PHS for research or educational activities must disclose – before submitting a proposal – any substantive financial conflict of interest that may reasonably affect how the project is carried out. A possible conflict of interest does not preclude acceptance of PHS funding, but appropriate safeguards may need to be implemented in certain situations.

DEFINITIONS

A potential Conflict of Interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the College such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Investigator means the principal investigator/project director, co-principal investigators, and any other person at the College who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

Significant Financial Interest (SFI) means anything of monetary value, including, but not limited to:

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 College responsibilities:

1. With regard to any publicly traded entity, 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;

2. With regard to any non-publicly traded entity, 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

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

In addition, Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their College responsibilities (and reimbursed or sponsored travel of the Investigator’s spouse and/or dependent children) over the previous twelve-month period, with such disclosure updated within thirty days of each subsequent occurrence, unless those expenses have been reimbursed 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. This travel-related disclosure preliminary must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. The Director of Sponsored Programs and Foundation Relations will request further information if needed.

SFI does not include:

1. Salary, royalties, or other remuneration from the College if the Investigator is currently employed or otherwise appointed by the College;

2. Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agencies, 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;

3. Income from service on advisory committees or review panels for federal, state, or local government agencies, 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;

4. Travel that is reimbursed or sponsored (as in a grant) by a federal, state or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

5. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and, does not constitute more than a five percent ownership interest in any single entity;

6. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $5,000; or

7. 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.
The above exclusions do not apply, however, if the compensation or transfer of an equity interest is conditioned upon a particular outcome in a sponsored research project, or is conditioned upon or affected by an Investigator’s institutional responsibilities.

A Financial Conflict of Interest exists when the College, through the designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

GUIDELINES

Disclosure Process

1. Each Investigator is required to disclose the following Significant Financial Interests:
   
a) Any Significant Financial Interest of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or

b) Any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or

c) Any Significant Financial Interest of the Investigator that would reasonably appear to be affected by the Investigator’s professional responsibilities on behalf of Earlham, as defined by the Final Rule and including but not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on Institutional panels.

Regardless of the above minimum requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

2. Each Investigator who is participating in or is planning to participate in Public Health Service-funded research is required to complete COI training prior to engaging in research related to any PHS-funded grant or cooperative agreement and at least every four years, and immediately when any of the following occur:
   
a) An Investigator is new to the College; or

b) Institutional FCOI policies change in a manner that affects Investigator requirements.

Investigators will be required to discuss the training materials with and submit certification of completion of training to the Director of Sponsored Programs and Foundation Relations.

3. Each Investigator who is participating in or is planning to participate in Public Health Service funded research shall complete the PHS Financial Interests Disclosure Form and attach all required supporting documentation.

4. As required by the federal regulation, all Significant Financial Interests must be disclosed prior to the time a proposal is submitted. The institutional official will not sign off on the proposal until the Financial Disclosure Form has been completed and turned in. All financial disclosures must be updated annually by Investigators during the period of the award and within 30 days of discovering or acquiring a new reportable Significant Financial Interest.

5. Collaborators from other institutions (subrecipients, subgrantees, subcontractors and consortium members) must also be in compliance with Federal policies regarding investigator Significant Financial
Interest disclosure and their portion of the project must be in compliance with their institutional policies. Each collaborating institution will be required to demonstrate compliance with this requirement prior to being included as a subawardee or subcontractor on an Earlhams proposal to a PHS agency.

**Review of Financial Disclosures**

6. The Director of Sponsored Programs and Foundation Relations shall perform an initial review of all financial disclosures to determine whether an actual or potential conflict of interest exists. An actual or potential conflict of interest exists when the review reasonably determines that a Significant Financial Interest could directly affect the design, conduct, or reporting of the proposed sponsored project or the Investigator’s other Institutional responsibilities. If the initial determination is made that a Significant Financial Interest exists that could affect the design, conduct or reporting of these activities, then the Disclosure materials will be forwarded to the Academic Dean for further analysis.

**Management of Financial Conflicts of Interest**

7. In the event that a conflict of interest is identified, the Academic Dean shall determine what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests. Prior to consideration by the Academic Dean, the Investigator, in cooperation with the appropriate representative from the College, shall develop and present to the Academic Dean an FCOI 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 Management Plan shall address such issues as:
   a) Public disclosure of Significant Financial Interests;
   b) Review of research protocol by independent reviewers; and
   c) Monitoring of research by independent reviewers.

The Academic Dean shall review the Management Plan and approve it and add conditions or restrictions which may include the following:
   a) Modification of the research plan;
   b) Disqualification from participation in all or a portion of the research funded;
   c) Divestiture of Significant Financial Interests; or
   d) Severance of relationships that create actual or potential conflicts of interest.

If the Academic Dean determines that imposing the above referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Academic Dean may recommend that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions.

8. The approved Management Plan shall be incorporated into a Memorandum of Understanding between Earlham and the Investigator that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity. The Memorandum of Understanding shall be signed by the Investigator, the Department Convener or Program Director, and the Academic Dean. The Director of Sponsored Programs and Foundation Relations will certify that actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to forwarding to the Controller approval for expending any funds from the applicable federal award, or they will be disclosed to the sponsoring agency for action.

9. Whenever an Investigator has violated this policy or the terms of the Memorandum of Understanding, the Academic Dean shall recommend sanctions which may include disciplinary
action ranging from a public letter of reprimand to dismissal and termination of employment. If the violation results in a collateral proceeding under College policies regarding misconduct in science, then the Academic Dean shall defer a decision on sanctions until the misconduct in science process is completed. The Academic Dean's recommendations on sanctions shall be presented to the President who, in consultation with the Academic Dean shall enforce any disciplinary action.

**Reporting and Record Retention**

10. The College shall provide initial and ongoing FCOI reports to the PHS as required by §50.605(b).

11. Records of Investigator financial disclosures, and of actions taken to manage actual or potential conflicts of interest, shall be retained by the Director of Sponsored Programs and Foundation Relations until three (3) years after of the termination or completion of the award and submission of the final expenditure report to which they relate, or the resolution of any government action involving those records, whichever comes later.

*Revised and Approved August 2013.*