The following policy pertains to all Investigators of Earlham College who apply to or receive external research support from federal agencies that require Financial Conflict of Interest (FCOI) declarations. The Institutional Official (IO) is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or mitigated. The Director of Sponsored Programs and Foundation Relations will assist the IO in facilitating Investigator compliance with the College FCOI policy through reminders to required Investigators and retention of applicable records.

**Federal Regulations and Institutional Responsibilities**

Federal regulations governing grants from certain federal agencies (e.g. National Science Foundation (NSF) and Public Health Service (PHS) agencies including the National Institutes of Health (NIH)) require that the College adopt, monitor, and enforce an FCOI Policy covering financial conflicts that may arise as a result of research funded by such agencies. This policy implements the requirements of 2011 revised PHS Regulations 42 CFR 50, Subpart F (https://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf) and 45 CFR 94 (https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl); where there are substantive differences between this policy and the requirements, the requirements will take precedence.

**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.

Family includes any member of the Investigator’s immediate family, specifically, any dependent children, spouse or domestic partner.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that the College reasonably determines could directly and significantly affect the design, conduct or reporting of the externally sponsored research.

Financial Interest includes:

- Anything of monetary value received or held by an Investigator or an Investigator’s family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock
options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

- Any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

- and DOES NOT INCLUDE:
  
  a) salary, royalties, or other remuneration from the College;
  b) income from the authorship of academic or scholarly works;
  c) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles;
  d) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, medical centers, and research institutes; or
  e) income from service on advisory committees or review panels for U.S. Federal, state, or local government agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, medical centers, and research institutes.

Institutional Official (IO): The individual within the College who is responsible for the review of disclosures of significant financial interest. For the purposes of this policy, the IO is designated as the Academic Dean.

Institutional Responsibilities: The Investigator’s responsibilities associated with their College appointment or position, including but not limited to research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator: Any individual who is responsible for the design, conduct, or reporting of research sponsored by the federal agencies specified above, or proposals for such funding, and where agency funds flow through the College for management and distribution.

Research for the purposes of this policy is defined as a systematic investigation, study, or experiment designed to 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).

*Significant Financial Interest* is defined as a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds $5,000; or

b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds $5,000; or

c) if with a non-publicly traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or

d) is income related to intellectual property rights and interests not reimbursed through the College.

**Procedures**

All Investigators who apply for or receive grants from the Federal agencies identified above are required to follow the procedures set forth below.

1. **Disclosures of Significant Financial Interests**

   Using the College’s FCOI Disclosure Form, each Investigator will disclose all Significant Financial Interests:
   - that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by the grant source; or
   - in entities whose financial interests would reasonably appear to be affected by such activities.

   The disclosure form can be completed here: [Financial Conflict of Interest Form](#).

2. **Disclosures of Travel**

   Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities. Travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers need not be disclosed. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The IO will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes an FCOI with the Investigator’s research.
3. Timing of Disclosures

Investigators and designated personnel are required to complete FCOI disclosures as follows:

a. Prior to submission of a proposal to the designated external funding agency.
b. Annually for funded grants: In September of each year, Investigators will complete an updated FCOI Disclosure Form.
c. Within 30 days of acquiring or discovering any new reportable Significant Financial Interests.
d. Investigators joining the College who are conducting research sponsored by the agencies to which this policy applies will provide all necessary disclosures within 30 days.

4. Review of Disclosures

The Director of Sponsored Programs and Foundation Relations will perform an initial review of all financial disclosures to determine whether any potential conflicts of interest were disclosed. If so, the Institutional Official will review financial disclosures prior to the expenditure of any funds and determine whether an FCOI exists. An FCOI exists if the IO or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally-supported research.

Review, determination of whether a conflict exists, and creation and implementation of management plan will occur within sixty (60) days of submission of FCOI disclosure form.

5. Management Plans

If the Institutional Official determines that there is are any FCOI(s), they must approve a written management plan to manage, reduce or eliminate the conflict before any related research goes forward. Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, and protect the sensitivity of disclosed information. The affected Investigator is responsible for developing and submitting a proposed management plan to, and in consultation with, the IO. Management Plans may include one or more elements, such as the following:

- Public disclosure of conflicts when presenting or publishing research;
- Monitoring of the sponsored program by independent reviewers;
- Modifications to the research or program plan;
- Appointment of an oversight panel or person to review research/scholarship;
Limitations on the Investigator's involvement in all or a portion of the funded research or program;
Divestiture of Significant Financial Interests;
Severance of relationships that create actual or potential conflicts of interest; and/or
Other arrangements that manage, reduce, or eliminate a potential Financial Conflict of Interest.

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.

**Reporting to a Federal Agency**

If any identified conflict or non-compliance requires reporting to the sponsoring federal agency, the IO will produce such a report in accordance with applicable regulations.

**Investigator Non-compliance**

1. Disciplinary Action

   If an Investigator fails to comply with this Policy, the Institutional Official may suspend all relevant activities until the matter is resolved. Further, the IO may recommend disciplinary action for failure to comply with this policy, ranging from a public letter of reprimand to dismissal and termination of employment. The decision to impose sanctions on an Investigator will 1) be described in writing to the Investigator and 2) notify the individual of their right to appeal the decision. If the violation results in a collateral proceeding under College policies regarding Research Misconduct then the IO will defer a decision on sanctions until the misconduct review proceedings are completed and decide upon sanctions under guidance of College FCOI and Research Misconduct policies.

2. Retrospective Review

   In some cases, the IO may determine that an FCOI was not identified or managed in a timely manner, including but not limited to an Investigator’s failure to disclose a Significant Financial Interest that is determined to be an FCOI, or an Investigator’s
failure to materially comply with their approved FCOI Management Plan. In such cases a committee appointed by the IO will complete a retrospective review of the Investigator's activities and the research project within 120 days of determination of non-compliance to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review will include the project number, project title, PI, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The IO will update any previously submitted report to the funding agency, specifying the actions that will be taken to manage the FCOI going forward. If bias by the investigator is found, the report will include a mitigation report in accordance with the applicable regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

**Training**

Each Investigator federally required to participate in FCOI disclosure is required to complete FCOI training prior to starting the federally funded project and at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the IO in the event of substantial changes to the College FCOI policy.

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

**Record Retention**

All disclosure forms, conflict management plans, and related documents will be retained by the Director of Sponsored Programs and Foundation Relations for a period of 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.

**Confidentiality**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be kept confidential. However, the College may make such information available to the agency funding the research or to a requestor of information concerning financial conflict of interest related to relevant federal funding, if requested or required. If the College is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.
Public Accessibility

The information to be made available will be consistent with the requirements of the applicable federal regulation or official funding agency policy. The College will respond to any requestor within five (5) business days of the request, with information concerning any Significant Financial Interest that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the Investigator;
- A determination has been made that the Significant Financial Interest is related to the federally funded research; and
- A determination has been made that the Significant Financial Interest is an FCOI.

Subrecipients and Subawardees

When the College works with subrecipients or subawardees of grant funds from the federal agencies to which this Policy applies, it will enter into written agreements specifying whether the subrecipient institution will follow College’s FCOI Policy or its own. Subrecipients and subawardees will be required to comply with any applicable federal regulations.

Policy review. This policy is to be reviewed at least every three years. Review will be initiated by the Office of Sponsored Programs and Foundation Relations.

Approval of policy revision by the Academic Dean on May 25, 2018.