

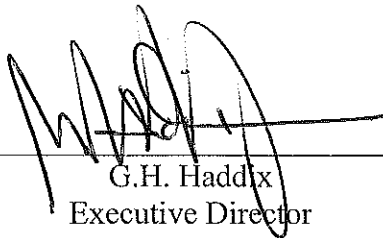
COLUMBUS CCOP FINANCIAL CONFLICT OF INTEREST POLICY

Federal Regulation #	POLICY No.: CCOP-014
42 CFR Part 50, Subpart F	Version No.: 1.1
45 CFR Part 94	Effective Date: 01/02/13

Purpose/Scope of Procedures:

The policy outlined below is intended to meet the most recent published Federal government requirements regarding Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research on August 25, 2011 (42 CFR Part 50 Subpart F and 45 CFR Part 94).

Department Approvals:



G.H. Haddix
Executive Director



Columbus CCOP Board of Directors
Board Chair

or
Chair of Policies & Procedures Committee

THIS PAGE IS BLANK



COLUMBUS CCOP FINANCIAL CONFLICT OF INTEREST POLICY

Federal Regulation #	POLICY No.: CCOP-014
42 CFR Part 50, Subpart F	Version No.: 1.1
45 CFR Part 94	Effective Date: 01/02/13

Definitions:

Authorized Organization Representative (AOR): The individual or Signatory Official, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

Financial Conflict of Interest (FCOI): a situation in which an Investigator has a significant financial interest or other personal involvement that would directly compromise, or have the appearance of compromising, his or her professional judgment or integrity in designing, conducting, or reporting research.

Significant Financial Interest (SFI): Any of the following financial interests of any key research personnel, or his or her immediate family, in aggregate. (The thresholds described below apply to the aggregate ownership of a key research personnel and his / her immediate family. For example, if an Investigator, his/her spouse, domestic partner and dependent children own together \$5,000 worth of equities in the sponsor and/or its affiliated companies). The thresholds do not apply to the combined ownership of all Investigators or Key Research Personnel.

- Income in excess of \$5,000 from a publicly-traded entity (a company whose stock is available for purchase by general public) during past 12 months.
- Stock values in excess of \$5,000 at the time of disclosure in a publicly traded entity.
- A combination of the above two items (stock and income) that exceeds \$5,000.
- Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity (such as a start-up company).
- Compensation that exceeds \$5,000 from a non-publicly traded entity in the past 12 months.
- Income related to intellectual property rights paid by any source other than the investigators or Key Research Personnel's current institution.
- Any reimbursed or sponsored travel paid by an entity, including non-profit organizations, but excluding travel sponsored by or reimbursed by a government agency, a U.S. institution or higher education or a research institute affiliated with such, a medical center or an academic teaching hospital. The specific details that must be disclosed are: the name of the entity sponsoring the travel and purpose, destination, and duration of the travel.
- Any other interests required under the Institutional policy.



COLUMBUS CCOP FINANCIAL CONFLICT OF INTEREST POLICY

Federal Regulation #	POLICY No.: CCOP-014
42 CFR Part 50, Subpart F	Version No.: 1.1
45 CFR Part 94	Effective Date: 01/02/13

Institution refers to any organization that is applying for or that receives NIH research funding. For the purposes of this policy, “Institution” refers to the Columbus CCOP, which includes the CCOP office in Columbus, OH as well as all affiliate sites.

Institutional Responsibilities means any of the professional responsibilities of a covered individual on behalf of the Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, or service on an institutional panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

Key Research Personnel: The term means the project director or principal investigator or any other person including but not limited to an investigator, regardless of title or position, who is responsible for the design, conduct or reporting of research activities funded or proposed for funding at the Columbus CCOP.

For the purpose of this policy, an investigator is defined as any participating investigator who has current, approved NCI Registration membership who has the potential to enroll patients on NIH clinical trials and be involved in the research program and activities funded by the NCI through the Columbus CCOP grant.

Sub-Recipients: Affiliate institutions of the Columbus CCOP including their components and affiliated treatment sites.



COLUMBUS CCOP FINANCIAL CONFLICT OF INTEREST POLICY

Federal Regulation #	POLICY No.: CCOP-014
42 CFR Part 50, Subpart F	Version No.: 1.1
45 CFR Part 94	Effective Date: 01/02/13

Responsibility:	Action:
<ul style="list-style-type: none"> ○ CCOP Board of Directors ○ CCOP employees ○ CCOP IRB members ○ CCOP Investigators ○ CCOP Nurses ○ Data Managers 	<p><u>Policy:</u></p> <p>The Columbus CCOP will promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as 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 research funded by PHS (Public Health Service), or proposed for such funding, which may include, for example, collaborators or consultants.</p> <p>The Columbus CCOP certifies the compliance to this policy by:</p> <ol style="list-style-type: none"> 1. Maintaining an up-to-date, written and enforced administrative process to identify and manage Financial Conflicts of Interest (FCOI) with respect to all research projects for which NIH funding is sought or received; 2. Promoting and enforcing Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests; 3. Identifying and managing financial conflicts of interest and provide initial and ongoing FCOI reports to the NIH consistent with this subpart; 4. Promptly making information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a Financial Conflict of Interest, when requested. 5. Fully complying with the requirements of the regulation.