

## COLUMBUS NCORP FINANCIAL CONFLICT OF INTEREST PROCEDURES

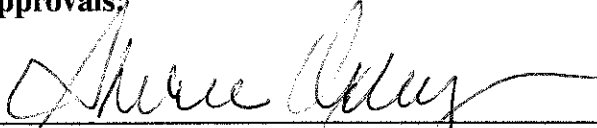
<b>Federal Regulation #</b>	<b>SOP No.: NCORP-014.1</b>
42 CFR Part 50 Subpart F	<b>Version No.: 1.2</b>
45 CFR Part 94	<b>Effective Date: 11/11/14</b>

**Purpose/Scope of Procedures:**

The primary goal of the Columbus NCORP Financial Conflict of Interest Policy is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health System grants, cooperative agreements and contracts will be free from bias resulting from potential Investigator financial conflicts of interest.

The standard operating procedures outlined below are 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:**

  
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 Sheree Oxley, RN, BSN, MS  
 Executive Director

  
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 Columbus NCORP Board of Directors  
 Board Chair

**Procedure Change History:**

11/11/2014

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**Authorized Organization Representative (AOR):** The individual or Signatory Official (SO), 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.

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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 NCORP, which includes the NCORP 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 NCORP.

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 NCORP grant.

Sub-Recipients: Affiliate sites of the Columbus NCORP with current FWA documentation and membership agreements.



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Responsibility:	Action:
	<p>its FCOI policy that affects the requirements of Key Research Personnel;</p> <ul style="list-style-type: none"> <li>c. When a new investigator becomes part of the Columbus NCORP;</li> <li>d. When an investigator is not in compliance of the FCOI policy.</li> </ul> <p>3. The Columbus NCORP requires all key research personnel to provide verification of their certified FCOI training:</p> <ul style="list-style-type: none"> <li>e. By submission of the printed NIH or CITI training module completion certificate to the Columbus NCORP Office;</li> <li>f. By providing written verification from the FCOI regulatory personnel of the Affiliate Institution where the Investigator practices.</li> </ul> <p>4. The Columbus NCORP requires all key research personnel to read its FCOI policy and submit a Columbus NCORP SFI disclosure form:</p> <ul style="list-style-type: none"> <li>g. Annually during his/her affiliation with the Columbus NCORP;</li> <li>h. Within 30 days of identifying or acquiring a new SFI.</li> </ul> <p><b>Section II FCOI DISCLOSURE, MONITORING, ENFORCEMENT, RECORD RETENTION</b></p> <ul style="list-style-type: none"> <li>1. The Columbus NCORP AOR will appoint and delegate authority to a FCOI authority to administer the FCOI procedures and submit the FCOI reports to the NIH.</li> <li>2. The Columbus NCORP FCOI authority will collect and review disclosures of SFIs of key research personnel to determine whether a SFI is related to PHS-funded research and if it is a FCOI.</li> <li>3. All suspect SFIs will be forwarded to the FCOI Review Committee which consists of the Executive Director, the Research Data Compliance Manager, a member of the Executive Committee of the NCORP Board of Directors and the designated FCOI authority. The FCOI Review Committee will meet quarterly and/or within 60 days of receipt of potential SFIs for the purpose of: <ul style="list-style-type: none"> <li>a. Reviewing any instances of non-compliance with this policy and develop a management plan.</li> </ul> </li> </ul>

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Responsibility:	Action:
	<ul style="list-style-type: none"> <li>b. Determining and implementing any or all of the sanctions or corrective action for non-compliance listed below:               <ul style="list-style-type: none"> <li>i. Written reprimand</li> <li>ii. Suspension of project funding</li> <li>iii. Suspension of research study</li> <li>iv. Restriction of privileges</li> <li>v. Suspension of membership of the Columbus NCORP.</li> <li>vi. Other appropriate sanctions or discipline, depending on the severity and nature of the non-compliance.</li> <li>vii. Notification of non-compliance to the research sponsor.</li> </ul> </li> <li>4. The FCOI Review Committee will complete and document retrospective reviews within 120 days of the Columbus NCORP's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.</li> <li>5. The Columbus NCORP requires all key research personnel with an FCOI that was not managed or reported as required by the regulation will:               <ul style="list-style-type: none"> <li>a. Disclose the FCOI in each public presentation of the results of the research.</li> <li>b. Request an addendum to previously published presentations.</li> </ul> </li> <li>6. The Columbus NCORP requires all FCOI-related records to be maintained on premise for at least 3 years from the date the final expenditures report is submitted to NIH.</li> </ul> <p><b>Section III REPORTING TO NIH, PUBLIC ACCESSABILITY</b></p> <ul style="list-style-type: none"> <li>1. The Columbus NCORP will submit initial, annual, and revised FCOI reports to the NIH for the Institution and its sub-recipients, if applicable, as required by the regulation:               <ul style="list-style-type: none"> <li>a. Prior to expenditure of funds</li> <li>b. Within 60 days of identification for an Investigator who is newly participating in the projects</li> <li>c. Within 60 days for new, or newly identified FCOIs</li> </ul> </li> </ul>

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Responsibility:	Action:
	<p>for existing investigators</p> <ul style="list-style-type: none"> <li>d. At least annually at the same time as when the Columbus NCORP is required to submit the annual progress report to provide the status of the FCOI and any changes to the management plan</li> <li>e. Provide a retrospective review within 120 days of discovery of a previously unreported FCOI, if appropriate.</li> </ul> <ol style="list-style-type: none"> <li>2. The Columbus NCORP will notify the NIH if bias is found with the design, conduct or reporting of NIH-funded research in accordance with the regulation.</li> <li>3. The Columbus NCORP will make its FCOI policy accessible by:               <ul style="list-style-type: none"> <li>a. Posting the policy on the Columbus NCORP website: <a href="http://www.columbusccop.org">www.columbusccop.org</a></li> <li>b. Updating it at least annually.</li> </ul> </li> <li>4. The Columbus NCORP will make information concerning identified FCOIs held by key research personnel publicly accessible:               <ul style="list-style-type: none"> <li>a. By posting it on its website with updates at least annually and within 60 days of newly identified FCOIs for at least three years from the date the information was most recently updated prior to the expenditure of grant funds.</li> </ul> </li> </ol>