CANCER RESEARCH FOR THE OZARKS (CRO)
STANDARD OPERATING PROCEDURE (SOP) #18
Financial Conflict of Interest (FCOI)

1. INTRODUCTION AND PURPOSE

Research activities supported by NCI grants and contracts (including sponsored trial agreements) provide a valuable source of funding for Cancer Research for the Ozarks. Scientific credibility and acceptance of the results of a clinical investigation depend upon the integrity and objectivity of the investigators and research staff. Due to the sophistication and complexity of clinical research, individuals involved in research activities have an increased potential for conflicting interests.

It is the purpose of this policy to set forth the principles for identifying those individuals who should report significant financial interests and situations that may pose a potential for conflicts of interest in compliance with applicable federal laws, regulations, and policies.

2. SCOPE

This SOP promotes objectivity in research by recognizing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from investigator and/or research staff financial conflicts of interest. The policy and procedures outlined below are intended to meet the requirements published by the federal government regarding Financial Conflict of Interest (FCOI) regulations including Public Health Service, Department of Health and Human Services, Grants, Policies of General Applicability, Promoting Objectivity in Research (42 CFR Part 50 Subpart F) and Public Welfare, Department of Health and Human Services, General Administration, Responsible Prospective Contractors (45 CFR Part 94).

3. APPLICABLE REGULATIONS AND GUIDELINES

42 CFR, Chapter I, Subchapter D, Part 50, Subpart F	Promoting Objectivity in Research	Source 76 FR 53283 08-25-11 Amended 81 FR 3006 01-20-16
45 CFR, Subtitle A, Subchapter A, Part 94	Responsible Prospective Contractors	Source 76 FR 53288 08-25-11
45 CFR, Subtitle A, Subchapter A, Part 94.4	Responsibilities of Institutions Regarding Investigator Financial Conflicts of Interest	Source 76 FR 53288 08-25-11

4. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in the Financial Conflict of Interest determination including the following:

- CRO Principal Investigator
- Research Investigators
- CRO Director
- MIRB members and staff
- CRO Executive Board
- Compliance Officers at Mercy Springfield and CoxHealth
- Institutional Administrator (at location of Research Investigator)

5. DEFINITIONS

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

Research Investigator means 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 the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. To illustrate, this will include any individual who has the potential to enroll patients on NIH clinical trials, is employed by CRO, or works in a research office of a sub recipient member that enrolls patients on NIH trials through CRO's NCI Community Oncology Research Program (NCORP) or otherwise fits this definition.

Significant Financial Interest means any current financial interest of a Research Investigator and his/her immediate family (Investigator's spouse and dependent children) that reasonably appears to be related to the Research Investigator's Institutional Responsibilities as defined in CFR 42, Chapter I, Subchapter D, Part 50, Subpart F and may include, but not be limited to, 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.

Significant financial interests might include, but are not limited to, any of the following:

- Direct equity interests (such as stock, stock options, or ownership interests) or renumeration of significant monetary value including salary or other payments for services (such as consulting fees, honoraria, or paid authorships) from publicly or non-publicly traded entities
- Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- Reimbursed or sponsored travel

6. PROCESS OVERVIEW OF PROCEDURES

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7. PROCEDURES

A. Disclosure

Responsible Team Members:	**Disclosure *of Significant Financial Interests***
• CRO Principal Investigator • Research Investigators	Research Investigators must reveal all current Significant Financial Interests (SFIs) either through direct reporting of SFIs to CRO or according to signed, written agreements between the Research Investigator's Institution and CRO. **Financial disclosure forms need to be submitted:** • Prior to approval as a CRO investigator • Annually • Whenever a new transaction or activity is proposed that might involve a potential Financial Conflict of Interest • Within thirty (30) days of the Research Investigator discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest. • Whenever CRO revises its FCOI policy that affects requirements of Research Investigators

B. Training

Responsible Team Members:	**Training**
• CRO Principal Investigator • Research Investigators	Research Investigators are required to undergo initial FCOI training and are required to be trained at least every 3 years. Training shall be completed at: https://about.citiprogram.org/en/homepage/

C. Disclosure Review and Monitoring

Responsible Team Members:	**Disclosure Review**
• CRO Principal Investigator • CRO Director • CRO Executive Board • Compliance Officers • MIRB COIS • Research Investigators • Institutional Administrator	CRO's Director will provide timely review of completed Significant Financial Interest Disclosure and will notify CRO Executive Board upon completion of such review. **Management Plans for reported Conflict of Interest** After reviewing an individual FCOI with possible conflict and discussion with the individual, the CRO Principal Investigator, CRO Director, and Compliance Officers will decide whether a management plan is needed. Should management of a potential or actual significant financial conflict of interest be required, the Research Investigator, Institutional Administrator (at location of Research Investigator), the CRO Principal Investigator, the CRO Director, and a Compliance Representative will draft a "Management Plan." Written plans will be created to manage, reduce, or eliminate the significant financial interest(s). Plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and

protect the confidentiality of disclosed information.

Draft management plans will be reviewed by the Mercy and CoxHealth Compliance Officers who will make a recommendation to the Mercy Institutional Review Board (MIRB) Conflict of Interest Subcommittee (COIS) advising whether to approve or reject the management plan.

All final management plans approved by the MIRB are reported to the CRO Executive Board who may require more stringent requirements be implemented to manage the Financial Conflict of Interest.

Management plans may include a single element or several elements such as:

- Limitations on the Research Investigator's involvement in personnel decisions on behalf of CRO
- Monitoring of the sponsored program by independent researchers, reviewers, or Compliance Officers
- Modifications to the research or program plan
- Appointment of an oversight panel or person to review research
- Public disclosure of Significant Financial Interests, including human research participants, researchers, publishers, and/or conference organizers
- Divesture of Significant Financial Interests
- Other arrangements that manage, reduce, or eliminate a potential Financial Conflict of Interest.

Dispute Resolution

If the person with the Financial Conflict of Interest, Institutional Administrator (at location of Research Investigator), the CRO Principal Investigator, the CRO Director, and a Compliance Officer cannot agree on a management plan, the matter will be referred to the Compliance Officers at Mercy Springfield and CoxHealth. In such cases, the Investigator may request that a CRO Executive Board member of his/her choosing (other than himself/herself) consult with the Compliance Officers for the review of the situation.

The Compliance Officers will review the written materials and consult with the Investigator, Institutional Administrator (at location of Research Investigator), CRO Principal Investigator, CRO Director and/or others as needed. The Compliance Officers will make a recommendation to the MIRB COIS and will notify the CRO Executive Board Member if involved. The MIRB COIS, after consideration of any involved parties, shall make the final determination on management plans.

D. Responsibilities of Compliance Officers and MIRB COIS

Responsible Team Members:	**The Mercy Compliance Officer and MIRB COIS have the following primary responsibilities:**
• Compliance Officers • MIRB COIS	• Review complex disclosures, as requested by CRO, to assure that all issues have been considered and addressed • Review all draft management plans and make a recommendation to the MIRB COIS whether to accept or reject the management plan. • In cases where the Investigator, Institutional Administrator (at location of Research Investigator), Principal Investigator, CRO Director, and Compliance Officers have been unable to reach agreement, the MIRB COIS will make a decision • The Mercy Compliance Officer will advise CRO Executive Board on implementation and communications regarding the FCOI policy and processes, in consultation with the CoxHealth Compliance Officer.

E. Enforcement

Responsible Team Members:	**Enforcement** Failure to properly disclose relevant financial interests or failure to adhere to conditions or restrictions imposed by a duly adopted management plan will be considered a deviation from accepted standards of conducting research at CRO. Alleged violations of this policy will be investigated by the Mercy Compliance Officer, in consultation with the CoxHealth Compliance Officer, who will make recommendations for action to the CRO Executive Board. The Mercy Compliance Officer will also report confirmed violations to the MIRB COIS for further action regarding any open study. **Breaches of policy include:** • Failure to file the necessary disclosure statements • Knowingly filing incomplete, erroneous, or misleading disclosure forms • Failure to comply with procedures prescribed by the CRO Director or other authorized party **In addition to actions the MIRB COIS takes regarding any studies, if the CRO Executive Board determines the policy has been violated, it may impose sanctions including, but not limited to:** • Suspension of enrollment privileges to NIH/CRO clinical trials • Formal admonition • Notification of sponsor • A letter to the investigator's personnel file • Within 120 days of determination of non-compliance, a retrospective review of the investigator's activities and the NIH-funded research project will be done to determine if there was bias in the design, conduct, or reporting of research.
• CRO Principal Investigator • CRO Director • Research Investigators • Compliance Officers • CRO Executive Board • MIRB COIS	

F. Reporting Requirements to NIH

Responsible Team Members: • CRO Principal investigator • CRO Director	**Reporting Requirements to NIH** CRO will provide initial and ongoing FCOI reports, as required by NIH policy, to NIH through the ERA Commons FCOI Module. **FCOI reports are submitted to NIH:** • Prior to the expenditure of funds during the award period • Within 60 days of identifying a new FCOI • To report on the status of FCOI and any changes in management plan(s) • With multi-year and annual progress report submissions • At time of grant extension • When a bias is found in the design, conduct, or reporting of a research project

G. Maintenance of Records

Responsible Team Members: • CRO Director • CRO Regulatory Coordinator • CRO Business Coordinator	**Maintenance of Records** Conflict of Interest disclosures will be tracked by the CRO Director, CRO Regulatory Coordinator, and/or CRO Business Coordinator and updated as changes occur. Records will be maintained for at least three years following the date the final expenditures report is submitted to PHS or other dates specified in 45 CFR 75.361. Records will not be routinely provided to sponsors unless such is an agency requirement and the agency submits a written request. The CRO Director will be responsible for communications with study sponsors. Disclosure statements and associated information will not be released without notification to the investigator.

H. Public Access

Responsible Team Members: • CRO Director • CRO Regulatory Coordinator • CRO Business Coordinator	**Public Access** Cancer Research for the Ozarks FCOI policy will be posted on the CRO web-site at www.ozarkscancerresearch.org **Information on FCOI of senior/key personnel will be accessible on the CRO website. This information shall minimally include the following:** • Investigator's name • Investigator's title and role with respect to the research project • Name of the entity in which the Significant Financial Interest (SFI) is held • Nature of the SFI (e.g. equity, consulting fees, travel reimbursement, honoraria, etc.) • Approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

I. Subrecipient

Responsible Team Members:	**Subrecipient**
• Research Investigators	CRO has Component agreements with hospitals and clinics. For the purposes of SOP # 18, the hospitals, clinics, physicians' groups, and research staff are considered sub-recipients of CRO's NCI grant. These institutions have their own research staff and CRO passes through funds from the NCORP grant for each accrual to NIH clinical trials accessed through CRO. The funds are paid directly to the health care entity. All Component investigators and research staff are to abide by SOP #18.