NCI Community Oncology Research Program – Kansas City (NCORP-KC)
Financial Conflict of Interest (FCOI) Policy Regarding NCORP-KC Responsibilities

(Version 1.0 Dated: 11/17/2014)
Approved by: Executive Director, Principal Investigator, & Board of Directors – NCORP-KC

I. Objective

1.1 The NCORP-KC is a not for profit organization supported by public funds awarded via the UG1 grant mechanism of the National Institutes of Health (NIH) - National Cancer Institute (NCI). The purpose of the NCORP-KC is to provide NCI sponsored clinical research trials to its member institutions and investigators throughout the Kansas City metropolitan area. The NCORP-KC is committed to preserving the public's trust by conducting research without bias and maintaining the highest ethical standards.

1.2 Identifying, managing, minimizing or eliminating financial conflicts of interest are important factors in assuring the public that the NCORP-KC and its investigators will uphold the integrity of clinical research. The Policy is a written and enforced administrative process to identify and manage FCOI, and to promote and enforce Investigator/senior personnel compliance. The NCORP-KC shall make reporting and review of FCOI an ongoing process and furnish information as requested to Health and Human Services per regulations.

1.3 This policy is intended to meet or exceed the recently updated expectations of the 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).

II. Significant Financial Interest

The U.S. Department of Health and Human Services (HHS) Final Rule on Financial Conflict of Interest Regulations defines **Significant Financial Interest** as:

2.1 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 institutional responsibilities, i.e. responsibilities related to NCORP-KC conducted research.

(a) With regard to any **publicly traded entity**, a significant financial interest 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 the 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;

(b) With regard to any **non-publicly traded entity**, a significant financial interest 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

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

2.2 Investigators also must disclose the occurrence of any **reimbursed or sponsored travel** (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored 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. The NCORP-KC's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the NCORP-KC FCOI policy, NCORP-KC FCOI compliance committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the Public Health Service-funded research.

Significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for profit organization; 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; income from seminars, lectures, or teaching engagements sponsored 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; or income from service on advisory committees or

review panels for 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.

III. Training Requirements

3.1 The NCORP-KC will electronically inform and remind all its investigators of the NCORP-KC policy, the federal requirement and the disclosure responsibilities of investigators on an annual basis.

3.2 All investigators will complete FCOI training prior to engaging in NCORP-KC research and at least every 4 years.

3.3 Immediate and repeat training will be necessary regardless of previous training for new investigators or if the institution devices FCOI policy that affects requirements of investigators or any time noncompliance is noted.

3.4 Investigators can provide evidence of FCOI training from their individual hospitals. CITI training is acceptable. National Institutes of Health conflicts of Interest tutorial 2011 and subsequent updates are acceptable. Other acceptable training will be determined from time to time by the FCOI committee.

3.5 Additionally, Investigators will review this policy annually at the time of FCOI disclosure.

IV. Public Accessibility Requirements

4.1 FCOI policy will remain posted on the NCORP-KC website at www.kccop.org and will not be password protected to allow full disclosure.

4.2 If the web site is not accessible due to technical reasons, the policy will be made available by the NCORP-KC at request to anyone, as soon as possible but within a maximum of 5 business days after the request is received.

4.3 Any modification of the NCORP-KC FCOI policy will be posted on its website within 30 days.

4.4 Annual disclosure and update of FCOI regarding key/senior personnel (as identified in the competing grant application) will be requested and if FCOI exists, federally required elements will be posted on the website or made available within 5 calendar days of a request.

4.5 Any FCOI information held by a senior/key personnel identified will be updated on the NCORP-KC website within 60 days and will remain available for three years from

the date the information was most recently updated. FCOI will however, be made available before expenditure of public funds.

V. Disclosure, Review and Monitoring Requirements

5.1 The NCORP-KC Administrative Assistant will request information regarding financial conflict of interest from all investigators and key/senior personnel annually.

5.2 All investigators and Key/Senior personnel must inform the NCORP-KC of any new FCOI as soon as possible but within a maximum of 30 days following identification of significant financial interest and no later than at the time of application for PHS funded research or expenditure of public funds.

5.3 FCOI forms will be submitted to the NCORP-KC Regulatory Coordinator who will then advise the Executive Director if significant financial interest exists. The Executive Director will determine if an investigators significant financial interest is related to PHS-funded research and, if so related, whether this constitutes FCOI. Assistance will be sought from FCOI committee comprised of the NCORP-KC Executive Director, Principal Investigator, Chairman of the Institutional Review Board, and Chairperson of the Board of Directors.

The FCOI committee may seek counsel from the National Institutes of Health/National Cancer Institute authorities in situations where a consensus cannot be obtained. Important consideration would be whether significant financial interest could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

5.4 The NCORP-KC FCOI committee will establish a management plan within 60 days whenever a significant financial interest was not reviewed timely or not reviewed by NCORP-KC. This plan will include besides discussion with the individual a modification to the research plan, and subsequent monitoring of the individual within federal guidelines.

VI. Maintenance of Records

6.1 FCOI related records will be maintained at the NCORP-KC office for at least 3 years from the date the final expenditures report is submitted to the National Institutes of Health and from other dates as required per the federal guidelines.

VII. Enforcement Mechanisms and Remedies and Noncompliance

7.1 The FCOI committee will recommend enforcement based on the level of conflict and noncompliance. Investigator sanctions with suspension of enrollment privileges, if felt necessary to preserve the integrity and ethics of clinical research may be necessary. Disclosure on the NCORP-KC website, monitoring by independent researchers,

divestiture of significant financial interest, limitation of personnel's involvement in the decision making related to activities of NCORP-KC may be some of the elements included in the suggested remedy.

A direct discussion with the investigator or personnel will be held by the Executive Director or the Principal Investigator.

If the investigator disputes recommendations of the FCOI committee, further guidance would be sought from the National Institutes of Health. In the interim, however, PHS research privileges will remain suspended till a final decision is made.

7.2 If non-compliance for significant financial interest disclosure is noted, retrospective review will be completed & documented within 120 days consistent with the federal regulation.

7.3 If the Department of Health and Human Services determines that a PHS-funded research with a purpose of evaluating safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an investigator with an FCOI that was not managed or reported by the NCORP-KC, the investigator will be required to disclose FCOI in each public presentation of the results of the research and provide an addendum to previously published presentations.

VIII. Reporting Requirements to NIH

8.1 Annually coinciding with submission of annual progress report, the Executive Director will summarize FCOI reports and send to the National Institutes of Health with elements required by the regulation.

8.2 This submission will be done prior to expenditure of PHS funds, within 60 days of a new investigator participating in research and within 60 days of a newly identified FCOI or following retrospective review to update a previously submitted report if necessary.

8.3 NCORP-KC will promptly notify the NIH if its investigators are noncompliant or found to be responsible for causing a bias in design, conduct or reporting of NIH-funded research. A mitigation report/Corrective Action Plan with elements required by regulation will be included, as completed by FCOI committee.

IX. Sub-Recipient Requirements

9.1 NCORP-KC membership includes investigators from multiple member hospitals. NCORP-KC provides NIH funds to member hospitals for conduct of clinical trials. The funds are meant to compensate hospitals for nursing and research personnel support. As such, these hospitals are identified as sub-recipients of public funds.

9.2 NCORP-KC will obtain a certification from each sub recipient hospital that the hospital FCOI policy complies with the Federal regulation and if any of the NCORP-KC investigators are noted to have an FCOI, NCORP-KC will be informed as soon as possible in a time frame that we will allow NCORP-KC to report FCOI to NIH as required by the regulation.