COOPER UNIVERSITY HEALTH CARE

Cooper Research Institute Policies and Procedures

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Section: Cooper Research Institute
Subject: R2 - Investigator Financial Disclosure and Conflict of Interest Policy

Notice: The official version of this Policy is contained in Cooper Policy Network and may have been revised since the document was printed.

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I. PURPOSE:

A. To set forth the Cooper University Health Care (CUHC) policy concerning investigator financial disclosure and conflict of interest that is in compliance with the Public Health Service (PHS) Objectivity in Research Final Rule (42 CFR Part 50 Subpart F and 42 CFR Part 94) and with the National Science Foundation (NSF) Investigator Financial Disclosure Policy, both effective January 1, 1995 and a Final Rule published in 2011, becoming effective August 24, 2012. The purpose of this policy is to determine and manage appropriately financial conflicts of interest among investigators applying for and receiving Federal and all other research, educational and service funds, thereby ensuring that the design, conduct and reporting of funded research, educational and service activities will not be biased by such conflicts.

II. ACCOUNTABILITY:

A. The Chief Physician Executive through the Cooper Research Institute Director shall ensure compliance with this policy.

III. APPLICABILITY:

A. This policy shall apply to all members of the CUHC staff and other employees who, on behalf of the CUHC, apply for or receive Federal or other funds, products or services

through a grant, subgrant, contract, subcontract, or cooperative agreement for any research, educational or service purpose.

B. It shall also apply to all investigators working on behalf of the CUHC as subgrantees, contractors, subcontractors or collaborators on projects funded or proposed for funding.

C. The policy shall apply to applications to all potential sponsors, including Federal and other governmental agencies, as well as voluntary agencies, private entities, foundations, the Office of Development and other internal sources.

D. The Policy shall also apply to all investigators who submit applications to the CUHC IRB for review and approval of research projects.

IV. DEFINITIONS:

A. **Investigator**

The term "investigator" shall mean:

1. The principal investigator,
2. Co-principal investigators, co-investigators, and
3. Any other person at CUHC who is or will be responsible for the design, conduct or reporting of funded or proposed research, educational or service activities proposed for funding by any internal or external sponsor; these persons may include all key study personnel such as, but not limited to:
    a. Research coordinators,
    b. Technicians,
    c. Consultants,
    d. Postdoctoral fellows, graduate and other students, etc.
4. For purposes of this Policy, the term "investigator" also includes the investigator's spouse and dependent children.

B. **Senior/Key Personnel**

1. This term refers to any person identified as senior/key personnel by CUHC in any grant application, progress report or any other report submitted on a Public Health Service funded research project.

C. **Reportable Significant Financial Interests**

1. The term "reportable significant financial interests" shall mean anything of monetary value including, but not limited to:
    a. Salary, royalties or other payments for services (e.g., consulting fees, paid authorship, honoraria, gifts of cash or goods, salary for an executive position on or for other employee position in a for-profit business, compensation for service on a Board of Directors or Scientific Advisory Board in a for-profit business, etc.) (Investigators must also 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), and the disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration).

b. Intellectual property rights (e.g., patents, copyrights and royalties from such rights),
c. Equity interests (e.g., stocks, stock options or other ownership interests) in business enterprises or entities.
d. Equity interests, including stock options, of any amount in a non-publicly-traded financially interested company (or entitlement to the same).

2. The term "reportable significant financial interests" shall NOT include:
   a. Salary, royalties or other remuneration from the CUHC;
   b. Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, or an accredited college or university (including an academic teaching hospital, a medical center or a research institution that is affiliated with an accredited college or university;
   c. Income from service on advisory committees or review panels for a federal, state or local government agency, or an accredited college or university (including an academic teaching hospital, a medical center or a research institution that is affiliated with an accredited college or university;
   d. Holdings in publicly traded, diversified mutual funds, pensions funds, or other investment funds over which the investigator does not directly exercise control over the investment decisions made in these vehicles.
3. A "*de minimis* financial interest" means a "reportable significant financial interest" which meets the following criteria:
   a. Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $5,000 during the next twelve-month period;
   b. Equity interests in any publicly traded entity that, when aggregated for the investigator and the investigator's spouse and dependent children does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value.

D. **Financially Interested Individual**

1. The term "financially interested individual" means an investigator who has a reportable financial interest.

E. **Financially Interested Company**

1. The term "financially interested company" means a commercial entity with financial interests -that would reasonably appear to be affected by the conduct or outcome of the research.

F. **Rebuttable Presumption**

The term "Rebuttable Presumption Against Financial Interests in Human Subject Research" shall mean:

1. The institution will presume that, in the absence of compelling circumstances, a financially interested individual who has reported more than a *de minimis* financial interest may not conduct human subjects research. A financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the Cooper University Health Care Research Ethics Committee, constitute compelling circumstances. The individual would then be allowed to conduct the research under conditions specified by the Cooper University Health Care Research Ethics Committee and approved by the responsible IRB.

G. **Compelling Circumstances**

1. The term "compelling circumstances" means facts considered by the Cooper University Health Care Research Ethics Committee that convince the Committee to allow an investigator with a reportable financial interest to conduct human subjects research.
2. Those facts include, but need not be limited to: the nature of the research; the magnitude of the financial interest and the degree to which it is related to the research; the degree to which the financial interest could be directly and substantially affected by the research; the degree of risk to subject's participating in the research; the extent to which the financial interest can be effectively overseen and managed; whether the investigator is uniquely qualified to conduct the research by virtue of experience and expertise; whether the research could otherwise be conducted safely or effectively without the investigator.
3. In reaching its determination the Committee will balance the potential benefits of the project and the investigator's participation in it with the risks to the subjects, risks to the integrity of the research data, risks of bias, and any risks which might be caused by the appearance of conflict.

H. **Prohibition of Payments for Results**

The term "Payments for Results" shall mean:

1. Payments conditioned upon particular research results or tied to desirable or preferred research outcomes;
2. Payments for subject enrollment or for referral of patients to research studies are permitted only to the extent such payments are:
    a. Reasonably related to costs incurred, as specified in the research agreement between the sponsor and the institution;
    b. Reflect the fair market value of services performed; and
    c. Are commensurate with the efforts of the individual(s) performing the research.

V. STATEMENT OF POLICY:

A. Investigators shall not apply for federally funded research, grants, education or service funds unless he/she has completed a financial disclosure form [Exhibit or Hyperlink] and any conflicts have been evaluated by the Research Ethics Committee. Investigators shall also comply with financial disclosure requirements of private foundations.

B. Investigators planning to participate in sponsored pharmaceutical or device clinical trials shall complete a financial disclosure form as part of the IRB submission.

C. No human subjects research shall be conducted by an investigator with a reportable financial interest unless the Cooper University Health Care Research Ethics Committee has found compelling circumstances, communicated its findings to the Cooper University Health Care IRB, and the IRB concurs with the Research Ethics Committee's compelling circumstances determination.

D. No research shall be conducted in Cooper University Health Care which includes payment for desired or preferred results.

E. Cooper University Health Care will not approve research protocols that:
    1. Limit the right of the principal investigator to receive, analyze and interpret all data generated in the research;
    2. Condition the right to publish on a preferred or desired outcome of the study; or
    3. Permit a sponsor or other financially interested company to require more than a reasonable period of prepublication review.

VI. POLICY IMPLEMENTATION:

A. Disclosure of Reportable Significant Financial Interests
    1. Responsibility to Disclose
        a. Each investigator planning to apply for or receiving funds for research, educational or service activities and all senior/key personnel on any PHS funded research project shall disclose to the Cooper Research Institute

Director all those reportable financial interests of the investigator and of the investigator's spouse and dependent children as described below:

i. That might reasonably appear to be affected by the research service or educational activities funded or proposed for funding; or

ii. In entities whose financial interests might reasonably appear to be affected by the research service or educational activities funded or proposed for funding.

iii. This reporting obligation shall also apply to non-human subject research, and, under the following circumstances, to pre-clinical research:

1. First, the non-human subject research is linked to any reportable financial interest, and:
2. Second, the pre-clinical research is reasonably anticipated to be (i) a component of an IND submission or (ii) progress to research involving human subjects within twelve (12) months.
3. When a reportable financial interest is disclosed in the context of non-human subject or pre-clinical research, the Research Ethics Committee shall have the authority to decide whether any of the policy stipulations that apply to human subjects research should apply to this research.

iv. The duty to disclose as provided for in this Policy shall also apply to research where an IRB other than a Cooper IRB is the designated IRB for the initial approval and continuing review of a research protocol. In such an instance, the Research Ethics Committee shall send its determination to the designated IRB, and also disseminate its determination as required in Section VI, B, 3,a below.

2. Timing of Disclosure

a. All of the above required financial disclosures shall have been provided by the investigator to the Cooper Research Institute Director **AT THE TIME THE PROPOSAL IS SUBMITTED TO THE FEDERAL FUNDING AGENCY or to a private foundation requiring such disclosure**. No proposal may be submitted to a federal funding agency without such disclosure. For sponsored clinical trials, financial

disclosure by investigators must be filed with application for IRB approval. Human subjects research projects will not be reviewed by the IRB prior to receipt of disclosures and resolution of conflicts of interest as necessary. Investigators with conflicts as defined herein are advised to file disclosures as early as possible to avoid unnecessary delay in IRB review.

3. Disclosure Form
    a. For federally funded or private foundation applications, the financial disclosure shall be made on a special Investigator Financial Disclosure Form that shall be submitted to the Cooper Research Institute Director prior to applying for funding. For all other studies, this electronic form can be found within Imedris, or successor system, the on-line research proposal submission system. A separate Investigator Financial Disclosure Form must be completed for each individual who is an "investigator" as that term is defined in Section IV, A above. If one or more such individuals had not been named at the time of proposal submission, a form or forms must be completed subsequently to the(se) individual(s) and submitted by the principal investigator to the Cooper Research Institute Director as soon as such individuals are assigned to the project.
    b. The Investigator Financial Disclosure Form shall contain sufficient information to determine whether the investigator's financial interests, if any, meet the definition of a "reportable financial interest" as defined in Section IV, C of this Policy, whether this financial interest is in entities whose financial interests might reasonably appear to be affected by the research, service or educational activity proposed, and how such a conflict of interest may be managed, reduced or eliminated.
    c. Prior to the submission to the Cooper Research Institute Director the Investigator Financial Disclosure Form shall be signed by the investigator and, if a conflict is indicated, by the Chief of the department or, if the investigator is a department Chief, Chief Physician Executive
    d. The Cooper Research Institute Director shall transmit the Investigator Financial Disclosure Forms to the Committee described in Section VI, B below when the information disclosed suggests that a reportable financial interest or other conflict of interest may exist. Those Investigator Financial Disclosure Forms which are not transmitted to the Committee

shall remain on file in the office of the Cooper Research Institute Director.

e. Each investigator shall be responsible for updating his/her Investigator Financial Disclosure Form during the period of the award and submitting it to the Cooper Research Institute Director on an as needed basis, within 30 days of discovering or acquiring, disclosing any new reportable financial interest obtained or any changes in the investigator's situation with respect to a previously disclosed potential conflict of interest since the original financial disclosure made at the time of submission of the proposal.

B. Review of Financial Disclosures and Resolution of Conflicts Revealed

Review of any financial disclosures, determination of whether a conflict of interest exists, and the management, reduction or elimination of any conflicts must be completed **PRIOR TO EXPENDITURE OF ANY AWARDED FUNDS. Human subjects Research Projects will not be reviewed by the IRB until financial disclosures have been received by the Cooper Research Institute Director and where a significant financial -interest has been identified, the Cooper University Health Care Research Ethics Committee has reviewed the financial interest, and, where applicable has made recommendations to manage, reduce or eliminate the conflict caused by the reportable financial interest.**

1. Scope of the Committee

The Cooper University Health Care Research Ethics Committee (hereinafter "the Committee") will:

a. Review financial disclosures from investigators that have been referred by the Cooper Research Institute Director

b. Determine whether a reportable financial interest exists, which reasonably appears to affect the design, conduct or reporting of the research, service or educational activities.

c. In the case of human subjects research determine whether in the event of a reportable financial interest, there are nonetheless compelling circumstance for allowing the research to proceed pursuant to such conditions as may be imposed by the Committee.

d. Recommend what conditions or restrictions should be imposed upon the investigator to manage, reduce or eliminate such conflicts of interest. Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include, but are not limited to:

i. Disclosure of the reportable financial interest to:

1. State and federal officials, as required by state or federal regulation;
2. Research funders or sponsors;
3. If the study is part of multi-center trial, the Principal Investigator of the trial and the IRBs of the other participating institutions
4. To co-investigators and other staff working with the investigator on the project;
5. To the editors of any publication to which a manuscript concerning the project is submitted;
6. The public, in connection with any oral or written public communication of the research results;
7. To the research subjects in a manner sufficiently specific to identify the nature of the financial interest and that it has been reported to and is being managed by the institution;

ii. Monitoring of the research or educational activity by independent reviewers;
iii. Modification of the research plan or educational activity;
iv. Disqualification from participation in one or more elements of the research or educational activity (such as, restricting participation in subject recruitment or selection, consenting of subjects, analyzing or collecting data, or adverse event reporting, or, in the case of early-stage research, limiting participation to certain preliminary activities);
v. Divestiture of reportable financial interests or reduction of the amount of the interest to an acceptable level, of one exists;
vi. Deferral or waiver of payment to an investigator, or:
vii. Severance or limitation of the extent of relationships that create conflicts of interest.

2. Operations of the Committee
   a. While considering specific disclosures, the Committee may, subject to appropriate confidentiality restrictions, consult with individuals such as other members of the staff, scientists, experts in the field, the CUHC General Counsel, the Cooper Research Institute Director, the Chief Physician Executive, the Associate Dean for Research of the Cooper Medical School of Rowan University.

b. The Committee may ask the investigator to appear before it to provide additional details to assist in the Committee's determination about the existence of a conflict of interest and/or its recommendations concerning conditions or restrictions. It is expected that all faculty and staff will cooperate with the Committee.

3. Determination, Recommendations and Final Decision
   a. The Committee shall convey in writing its determination and recommendations and the reasons therefore to the IRB with copies to the investigator, Chief Physician Executive or his designee, appropriate Department Chief and Division Head.
   b. If the final decision is that a conflict of interest exists, but the research may proceed, the Cooper Research Institute Director shall report this to the funding agency prior to the expenditure of any funds under the award. The funding agency shall at the same time be assured that the conflict of interest has been managed, reduced or eliminated.
   c. If the final decision includes conditions or restrictions to manage, reduce or eliminate a conflict of interest, the investigator shall be required to document in writing to the Cooper Research Institute Director and the Cooper IRB his or her compliance with the condition or restriction prior to the expenditure of any funds under the award.
   d. Nothing in this policy shall be construed to limit or supersede the IRB's right, as part of its process of reviewing human subjects research, to: disapprove of a research project even though the Research Ethics Committee has found compelling circumstances to allow the research to proceed despite a conflict of interest, or place conditions on the approval of the research beyond those imposed by the Research Ethics Committee.
4. Subsequent Disclosures
   a. All investigators are required to immediately complete and submit a new Investigator Financial Disclosure form for any reportable financial interest which comes into existence while a funded research, service or educational protocol is pending. If there is a new reportable financial interest reported by the investigator subsequent to the initial disclosure, the same procedures for review of the disclosures, determination whether a conflict of interest exists, recommendations to manage, reduce or eliminate the conflict, and notification of the funding agency shall be followed as set forth in this Section. Such new conflicts must be managed, reduced or eliminated, at least on an interim basis, within sixty

(60) days of their identification. The Cooper Research Institute Direct shall notify the IRB if the new reportable financial interest reported is with a human subject research project. The research activity may be may be suspended or otherwise restricted during the investigation.

C. Training
   1. Training will be conducted via the Cooper Learning Network (CLN) and will be required of all investigators and key study personnel prior to their initiation of any government sponsored research. The course is entitled the Financial Conflict of Interest (FCOI) Tutorial.
      a. External investigators and study personnel will complete this training via the FCOI training site which is available at http://grants.nih.gov/grants/policy/coi/tutorial2011/Financial%20Conflict%20Of%20Interest%20-%20FCOI.pdf and will be required to email the completed certificate to the IRB.
   2. This training should be conducted every four (4) years thereafter and immediately under the designated circumstances:
      a. Institutional Financial Conflict of Interest policies change in a manner that affects the Investigator and key study personnel requirements;
      b. The investigator or key study personnel is new to an institution; and/or
      c. The Institution finds that an investigator is not in compliance with the institution's Financial Conflict of Interest policy or management plan.

D. Enforcement
   1. Failure to Submit
      a. Failure to fill out the required Investigator Financial Disclosure Forms shall prevent review by the IRB, or distribution of any funding received.
   2. Failure to Disclose
      a. Failure of any investigator to completely and truthfully fill out the Investigator Financial Disclosure Form shall be considered a breach of responsibility and shall be subject to the full range of disciplinary action, including, where applicable, notification of the funding agency and other interested parties.
   3. Failure to Comply
      a. If an investigator fails to comply with any conditions or restrictions imposed by decision of the Committee and IRB to manage conflicts of interest, or fails to comply with any other provision of this policy, **AND/OR** if such failure to comply has biased the design, conduct or reporting of the research, educational or service activity, the investigator

is subject to the full range of institutional disciplinary procedures as provided for in applicable CUHC disciplinary policies. The Cooper Research Institute Director shall inform the Committee and the Chief Physician Executive or his designee of such failure of compliance, who shall in turn make any notifications to any funding agency as may be necessary or appropriate under the circumstances. The Committee shall recommend corrective actions to be taken under these circumstances; the decision of the Chief Physician Executive or his designee about corrective actions shall be transmitted to the funding agency by the Cooper Research Institute Director.

b. In addition, where PHS-funded research is involved, the Committee will, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of noncompliance, was biased in the design, conduct, or reporting of such research and report the results of that review to the applicable federal agency.

4. Conflict Not Disclosed Prior to Research
   a. If clinical research with the purpose of evaluating the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an investigator with a conflicting interest that was not disclosed or not managed as set forth in this policy, the Chief Physician Executive or his designee shall, in addition to such other disciplinary action or notification initiated pursuant to this Policy, direct the investigator involved to disclose the conflicting interest in each public presentation of the research and to request an addendum to previously published presentations.

E. Reports and Record-Keeping
   1. Maintenance of Determinations and Recommendations
      a. The Cooper Research Institute Director shall maintain records of all financial disclosures, Committee determinations and recommendations, final decisions, actions taken to resolve conflicts of interest and the outcomes thereof for at least five (5) years from the date of submission of the final expenditure report of the project, or until the resolution of any government action involving those records, whichever is longer.
   2. Annual Reporting

a. Annually in January, the Cooper Research Institute Director shall summarize for the Chief Physician Executive all of the past year's financial disclosures, Committee determinations and recommendations, final decisions, actions taken and the outcomes thereof.

VII. RELATED POLICIES:

A. 1.138 - Institutional Financial Conflict of Interest in Human Subject Research
B. 12.101 - Provider Conflicts of Interest
C. 12.102 - Conflicts of Interest and Commitment

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