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Financial Conflict of Interest
Promoting Objectivity in Research Policy

Background
Institutions that apply for or participate in Public Health Service (PHS) funded research are subject to financial conflicts of interest regulations at 42 CFR Part 50 Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research for which National Institutes of Health (NIH) Funding is Sought.” The objectivity of researchers is an essential element in scientific research and the basis for public trust. The NIH requires institutions to establish and maintain a written enforced policy on conflict of interest. Furthermore, institutions are required to inform investigators of that policy along with the associated reporting responsibilities and report to the awarding offices the existence of any conflicting interest. The institution also must be able to assure that the conflict has been identified and managed, reduced, or eliminated in accordance with the established policy.

Purpose
The purpose of this policy is to strengthen the accountability and add transparency to investigators’ disclosure of Significant Financial Interests (SFI). The intent is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any SFI of an investigator. The Cooper Institute (Institution) chooses to extend the scope of this policy to include all research conducted at The Institute, regardless of funding source. The policy is intended to serve as a guide in structuring any business entities to avoid any appearance of conflicts of interest.

Definitions
A Significant Financial Interest (SFI) consists of the following financial interests of the Investigator and those of the Investigator’s spouse and dependent children that reasonably appear to be related to the Investigator’s Institutional responsibilities:

- In a publicly traded entity—the value of any remuneration received and the value of any equity interest in the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5000;
- In a non-publicly traded entity—the value of any remuneration received from the non-publicly traded entity in the 12 months preceding the date of disclosure, when aggregated, exceeds $5000; OR holds any equity interest (stock, stock option, or other ownership interest);
- Intellectual property rights and interests (patents, copyrights) upon receipt of income related to such rights and interests; or
- Travel related to their institutional responsibilities that is reimbursed or sponsored by an entity other than a federal, state, or local government agency, an institution of higher education, an academic training hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Financial Conflict of Interest (FCOI) is a SFI that could directly and significantly affect the design, conduct, or reporting of funded research.

Research is “any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge,” Code of Federal Regulations [CFR], Title 45, Part 46 Protection of Human Subjects, available at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.
*Investigator* is defined as the project director, principal investigator, and any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include collaborators or consultants. Investigator as used herein includes Cooper Institute employees as well as any consortium employee meeting the definition of investigator and thereby subject to FCOI requirements as agreed to in the signed subcontract or consultant agreement.

*Remuneration / Equity Interests* include salary, consulting fees, honoraria, paid authorship, stock, stock options, intellectual property rights and interests (copyrights or patents), or other ownership interest as determined via reference to public prices or other reasonable measures of fair market value.

Types of remuneration NOT covered by the regulations:
- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or appointed by the Institution;
- 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 retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, advisory committees, review panels, or teaching engagements sponsored by a federal, state, or local government agency, and 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.

*Investigator’s Institutional Responsibilities* means an Investigator’s professional responsibilities on behalf of the Institution, which may include, among other activities, research, research consultation, teaching, professional practice, and service on committees.

**Responsibilities**

**Institution Responsibilities.** The Cooper Institute will:
- Maintain an up-to-date, written policy on the FCOI regulations and make it available on a publicly accessible website
- Inform each Investigator of the policy and the responsibilities required regarding disclosure of SFIs
- Ensure each Investigator undergoes training on the FCOI regulations at least once every 4 years and prior to engaging in funded research
- Ensure each Investigator completes a Financial Disclosure Statement at least annually or within 30 days of acquiring a new SFI, and before submitting an application to a funding agency
- Take steps to ensure each subrecipient complies with FCOI regulations, either by subcontract agreement assurance or by requiring Financial Disclosure Statement forms from subrecipients before funds are spent
- The Designated Official (DO), as described in the Management Plan, will solicit and review disclosures of SFI
- Establish a Management Plan, described below, to make determinations on SFIs, take actions to manage FCOIs, and provide initial and ongoing reports to funding agencies
Certify compliance with the regulations in each PHS application
Make FCOIs available on a publicly accessible website for at least 3 years; update as needed or at least annually.

Investigator Responsibilities. The Investigator will:
- Complete a Financial Disclosure Statement at least annually, or within 30 days of acquiring a new SFI and before submitting an application to a funding agency
- Disclose to the DO any new SFIs that could affect funded research activities
- Disclose any travel that is reimbursed or sponsored by an entity OTHER THAN federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Designated Official / Conflict of Interest Committee
The Vice President for Research Administration (VPRA) will serve as the Designated Official (DO). A standing Financial Conflict of Interest committee will be formed by the VPRA, consisting of the DO, The Cooper Institute Chief Executive Officer, and The Cooper Institute Executive Vice President.

Disclosure statements from all Investigators will be maintained in the VPRA’s office at least 3 years, and longer if circumstances require. Any accompanying reviews, findings, determinations, reports, and actions will be filed with these records.

Financial Disclosure Statement
The Financial Disclosure Statement (attached) is a listing of the Investigator’s SFIs and those of the Investigator’s spouse and dependent children:
- That would reasonably appear to be affected by the research, and
- In entities whose financial interest would reasonably appear to be affected by the research.

The Financial Disclosure Statement is required to be updated as new SFIs occur, at least annually, and / or before applying for funded research. These will be kept on file in the DO’s office for at least 3 years.

Disclosure Requirements
Investigators. Investigators will be required to complete the Financial Disclosure Statement at least annually, within 30 days of a new event, and / or before applying for funded research.

Investigators are required to disclose any travel related to their institutional responsibilities that is reimbursed or sponsored by an entity OTHER THAN a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The disclosure must include the sponsor of the travel, destination, and duration of the travel, as well as any other requested information regarding the travel.

Institution. The Cooper Institute will ensure public access to FCOIs via a publicly accessible website. The FCOIs will be made available prior to expending any funds on the project and will be available for 3 years. The online disclosures will list:
- The Investigator’s name,
- Investigator’s title and role as related to the funded project,
- The name of the entity in which the SFI is held,
- The nature of the SFI,
The approximate dollar value of the SFI, if it can be determined. If a request regarding a SFI is received, The Cooper Institute will provide a written response to any requestor within 5 business days.

**Management Plan**

**Designated Official and Conflict of Interest Committee Responsibilities.** The DO will solicit and review Financial Disclosure Statements from all Investigators participating in or planning to participate in research. The DO will make the disclosures available to the Conflict of Interest committee and a meeting will be scheduled to review the Financial Disclosure Statement forms. If the Conflict of Interest committee reasonably determines from reviewing the Financial Disclosure Statements that a SFI could directly and significantly affect the design, conduct, or reporting of the funded research, it shall make one or more of the following determinations:

- Disclose FCOIs directly to participants of human subjects research and in the informed consent form,
- Disclose the FCOI to the public, via the publicly accessible website and/or as an addendum when presenting or publishing the research,
- Appoint an independent monitor to take measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI,
- Modify the research plan,
- Change the personnel or personnel responsibilities in the conduct of the research,
- Disqualify the Investigator from participation in all or part of the research,
- Reduce or eliminate the FCOI by requiring the Investigator to divest the SFI, and/or
- Sever the relationship that creates financial conflicts.

**Elements of the Management Plan.** The Management Plan will include:

- the role and function of the conflicted Investigator in the funded project,
- the rationale for including the conflicted Investigator in the funded project,
- the conditions of the Management Plan for the Investigator,
- how the Management Plan will ensure objectivity in the funded project,
- confirmation of the Investigator’s agreement of compliance to the Management Plan, and
- how the Management Plan will be monitored to ensure Investigator compliance.

The Conflict of Interest committee will decide which of the determinations listed above is/are best fit(s) for the Management Plan of the conflicted Investigator and how this will ensure objectivity of the funded project. When the report is written and agreed upon by all members of the Conflict of Interest committee, the conflicted Investigator will be required to sign the report and will be provided a copy. The DO will monitor the activities of the funded project and the conflicted Investigator to ensure compliance to the signed agreement. Monitoring may include obtaining copies of the informed consent, attending recruitment/orientation sessions, and/or obtaining reports from the data manager. If there is evidence of noncompliance with the Management Plan, other determinations will be enforced, up to and including removing the conflicted Investigator from the funded project and/or the Institution. The Investigator will also be required to undergo FCOI training immediately.

**Reports to Public Health Service and Other Funding Agencies**

The signature on a grant application by the signatory official will certify that The Cooper Institute is in compliance with the requirements of PHS regulations regarding FCOI. The DO will assure that by the time of application submission the DO has received a Financial Disclosure Statement from all Investigators named in the application. Before expenditure of any funds,
the DO will assure there are no FCOIs, or that they have been managed, reduced, or eliminated according to this policy.

- The DO will report within 60 days to the awarding component the existence of possible FCOIs and that the FCOIs are managed, reduced, or eliminated.
- If the Conflict of Interest committee determines that an investigator has biased the research, immediate notification will be made to the awarding agency of the corrective action to be taken to manage the FCOI.
- At least annual reports will be made to the funding agencies on any previously-identified FCOIs for the duration of the funded project.
- Reports will be made through the eRA Commons FCOI module.

Reports of FCOIs to the funding agencies will include the:
- Project number
- Principal investigator / project director of the funded study
- Investigator name
- Name of entity with which the Investigator has the FCOI
- Nature and value of the FCOI
- Description of how the FCOI relates to the funded research
- Key elements of the Management Plan applicable to this finding.

If any funding agency requests further information regarding any FCOIs, these requests will be fulfilled immediately.

Compliance Provisions
If a SFI is not disclosed by an Investigator within 30 days of discovering or acquiring the SFI, or if a subrecipient fails to review or report a SFI in a timely manner, the Management Plan will be immediately implemented. This can include all or some of the following:
- Conflict of Interest committee meeting,
- Notifying the funding agency,
- Making the SFI publicly accessible,
- Modify the research plan,
- Modify the personnel responsibilities,
- Appoint an independent monitor,
- Disqualify the Investigator from participation in all or part of the research,
- Require FCOI disclosure in each public presentation of the research and an addendum to any previously published presentations,
- Reduce or eliminate the FCOI by requiring the Investigator to divest the SFI, and / or
- Sever the relationship that creates financial conflicts.

This noncompliance review will be completed within 120 days from first determination.

Retrospective Review. An investigation into whether the research was biased before the FCOI was identified will be launched by the Conflict of Interest committee and appropriate sections of the Management Plan noted above implemented, if needed.

The components of the report from the Retrospective Review will include:
- Project number,
- Principal investigator / project director of the funded study,
- Investigator name,
- Name of entity with which the Investigator has the FCOI,
- Reason for the retrospective review,
- Detailed methodology used in the review: panel make-up, documents used, and findings and conclusions from the review.
Mitigation Report. If a bias is found, The Cooper Institute will immediately notify the funding agency and submit the mitigation report. The mitigation report will include the elements found in the retrospective review. Information on how the bias impacted the research will be included in the report and whether the Committee believes the research is salvageable. The action plan to eliminate or mitigate the effects of the bias will also be a part of the report. Reports will be submitted at least annually thereafter, or more often if changes occur or the circumstances require.
Background
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A Financial Conflict of Interest (FCOI) is a SFI that could directly and significantly affect the design, conduct, or reporting of funded research.
Please complete, sign, and return this page to Melba Morrow, Designated Official.

______I have no financial holdings or interests that meet the tests above.

______Financial holdings or interests that meet the tests above are listed below.

List all entities (excluding mutual or pension funds for which you have no influence on the selection of investments) in which you and/or your spouse and dependent children hold a Significant Financial Interest.

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I have read and understand The Cooper Institute’s Financial Conflict of Interest policy, have made all disclosures to the Vice President for Research Administration who is the Designated Official as required by the policy, and will comply with any conditions or restrictions imposed by the Conflict of Interest committee to manage, reduce, or eliminate actual or potential Financial Conflicts of Interest.

Investigator’s Name: ________________________________________________

Signature ____________________________

Date_______________________