UCONN HEALTH

POLICY NUMBER 2006-01
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POLICY: INDIVIDUAL FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

I. BACKGROUND:

Investigators and staff of UConn Health understand that their primary responsibility is to UConn Health and to its mission. Integral to that mission is the pursuit of research excellence and the dissemination of knowledge that emerges from research.

II. PURPOSE, APPLICABILITY and SCOPE:

This Policy on Individual Financial Conflicts of Interest in Research (hereinafter, the "Policy") promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any conflicting financial interest of an investigator.

UConn Health requires that all investigators promptly and fully disclose, in writing, any significant financial interest (including those of a spouse or dependent child) that reasonably relates to the investigator's institutional responsibilities and, if applicable, comply with financial conflict of interest management or mitigation plans.

This Policy applies to all investigators responsible for the design, conduct or reporting of research.

UConn Health institutional officials are obligated to identify and manage, reduce or eliminate any significant financial interest that could directly and significantly affect the design, conduct or reporting of research.

For further information regarding implementation please see the Policy's Guidance and Procedures document.

III. DEFINITIONS:

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

Financial Interest Related to the Research means financial interest in the sponsor, product or service being tested.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Human Subject (45 CFR Part 46) means a living individual about whom an investigator conducting research obtains: 1.) data through intervention or interaction with the individual, or 2.) identifiable private information. See also 21 CFR 50.

Institution means any domestic or foreign, public or private, entity or organization that is applying for or that receives extramural research funding**.**

Institutional Responsibilities means an investigator's professional responsibilities on behalf of the institution which may include research, research consultation teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.

Public Health Service means the Public Health Service of the U.S. Department of Health and Human Services (DHHS) and any components of PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH) and any other sponsor who requests application of the PHS FCOI regulation to the administration of their research awards.

PHS Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel on the grant application, progress report, or any other report submitted to the PHS by the institution.

Research means a systematic investigation, study or experiment, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Sponsor means an entity or organization that provides extramural funds for research.

Significant Financial Interest (SFI***)*** is defined as follows:

A. 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.

1. With regard to any **publicly traded entity**, an SFI 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 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;

2. With regard to any **non-publicly traded entity**, an SFI 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

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

B. Investigators governed by FDA regulations must disclose:

1. Compensation made to the investigator in which the value of compensation could be affected by the outcome of the study/research project.

2. A proprietary interest in the tested product, including but not limited to, a patent, trademark, copyright or licensing agreement.

3. Significant payments of other sorts, which are payments that have a cumulative monetary value of $25,000 or more made by the sponsor of a covered study to the investigator or the investigators' institution to support activities of the investigator exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for one year following completion of the study.

C. With regard to any **sponsored travel**, PHS-funded 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 if the value of any reimbursed or sponsored travel when aggregated, exceeds $5,000 from any single entity; 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. Details of this disclosure must include the purpose and duration of the trip, the identity of the sponsor/organizer, the destination and the duration.

D. This Policy does not apply to PHS Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications/awards.

E. **The term *significant financial interest* <u>does not</u> include** the following types of financial interests:

1. Salary, royalties, or other remuneration paid by UConn Health to the investigator if the investigator is currently employed or otherwise appointed by UConn Health, including intellectual property rights assigned to UConn Health and agreements to share in royalties related to such rights;

2. 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;

3. 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) https://www.gpo.gov/fdsys/pkg/USCODE-2011-title20/pdf/USCODE-2011-title20-chap28-subchapI-partA-sec1001.pdf, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or

4. 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) https://www.gpo.gov/fdsys/pkg/USCODE-2011-title20/pdf/USCODE-2011-title20-chap28-subchapI-partA-sec1001.pdf, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

IV. IMPLEMENTATION:

The Executive Vice President for Health Affairs (EVP) is responsible for overseeing the implementation and enforcement of this Policy.

The EVP has delegated implementation of the disclosure/review process to the Individual Financial COI in Research Management Committee (hereinafter referred to as the Committee) and its designees. The Committee is the designated institutional Office for purposes of soliciting and reviewing SFIs.

This policy is designed to identify actual or potential sources of individual significant financial conflicts of interest in research and to either eliminate, reduce or manage such conflicts. As such, the following procedures will be followed to assure compliance with this Policy and applicable state laws and sponsor regulations.

A. Notification: UConn Health's *Individual Financial COI in Research Policy* is publicly accessible via UConn Health's Web site at: http://health.uconn.edu/policies/wp-content/uploads/sites/28/2015/07/policy_2006_01.pdf

B. Training: Each investigator must complete training pursuant to PHS regulations 42 CFR 50.604(b) (1-3).

C. Sub-Recipient Investigators: If any portion of the extramurally funded research is performed by a sub-recipient, UConn Health will take reasonable steps to ensure that sub- recipient investigators comply with the sponsor's applicable financial COI policy and regulations.

UConn Health will establish by written agreement with the sub-recipient institution or investigator the applicable governing FCOI policy.

1. The sub-recipient will certify that its institution's FCOI policy complies with the respective sponsor's regulations and, further, that the sub-recipient will report identified FCOIs for investigators to UConn Health within thirty (30) days so that UConn Health has sufficient time to report those FCOIs to the sponsor.

2. Alternatively, if a sub-recipient lacks a sponsor-compliant FCOI policy, the sub-recipient investigator will be governed by this Policy.

D. Disclosure of Significant Financial Interests: Each investigator has an ongoing responsibility to disclose, in writing, all significant financial interests (SFIs), including any SFI of his or her spouse or dependent children that reasonably appear to be related to the investigator's institutional responsibilities. In considering whether an SFI should be disclosed, the investigator should consult the definition of SFI within this policy and, if in doubt, resolve in favor of disclosure. Investigators have a duty to cooperate fully with institutional officials regarding their requests for supplemental information and monitoring, if applicable, FCOI management plans.

1. **Annual Disclosure:** investigators have a responsibility to disclose and/or update reported SFIs annually.

2. **Upon Acquisition or Discovery:** Investigators have an on-going responsibility to disclose, within thirty (30) days, any newly acquired or discovered SFIs.

3. **Submission of Institutional Review Board Protocols (Human Subject Research):** Investigators, coordinators and persons obtaining consent must also file conflict of interest disclosure forms with the IRB at the time of initial review and at continuing review; and with a request for modification to add new staff, pursuant to UConn Health Human Subject Protection Office (HSPO) policies, as amended. If an investigator, coordinator or person obtaining consent makes a disclosure, the IRB will withhold final approval of the protocol until the Committee has made a determination and, if applicable, an agreed upon management plan is in place.

4. **Submission of PHS Research Proposals:** PHS investigators must disclose any previously undisclosed SFIs prior to submitting a proposal that has identified them as investigators; consistent with the requirements of 42 CFR 50.604 (3)(k)(1-5), the Office of Research and Sponsored Programs will certify in each PHS application that UConn Health is in compliance with PHS regulations.

5. **Prior to Engaging in Research:** Investigators must disclose all SFIs prior to engaging in any research project; new investigators who join on-going research projects must disclose all SFIs prior to beginning any research activity.

E. Review, Determination, Resolution and/or Management of FCOIs:

1. The Committee is appointed annually by the Executive Vice President for Health Affairs.

2. The Committee or its designee performs an initial administrative review.

3. The Committee or its designee shall review all SFIs to determine if the SFI is related to the sponsored research.

4. The Committee shall determine whether the SFI related to the sponsored research constitutes a FCOI.

5. The Committee will be authorized to request any other information that it deems necessary to assist it in its determinations.

6. The Committee may involve the investigator and/or his/her Department Head to assist in the determination of whether an SFI is related to research and/or constitutes an FCOI.

7. For review of disclosures of reimbursed or sponsored travel, the Committee may determine if further information is needed, including determination or disclosure of monetary value.

8. If the Committee determines that an FCOI exists, it will then determine what conditions or restrictions, if any, should be imposed by UConn Health to manage, mitigate, or eliminate such conflicts.

9. An FCOI must be eliminated or a management plan agreed to before a related award will be accepted and fund account established. Neither the institution nor an investigator may expend sponsor funds unless it has been determined that the FCOI has been eliminated or an FCOI management plan is in place.

10. The Committee or its designee will adequately document its determinations, recommendations, FCOI management plans and retrospective reviews.

F. Reconsideration/Appeals: In situations where an investigator disputes the decision of the Committee, the investigator may request that the Committee reconsider its determinations/recommendations as well as request permission to present his or her case in person. In the event the investigator disagrees with the Committee's decision, the investigator may appeal, in writing, to the EVP for Health Affairs, whose decision shall be final.

G. Notification/Reporting:

1. **Notification within UConn Health:** If a FCOI is identified as a result of the procedures outlined in this policy, the Committee or its designee is responsible for:

   a. Notification to the researcher of the management plan designed by the Committee for his/her FCOI;
   b. Notification to the Associate Vice President for Research Administration and Finance and to the Office of Research and Sponsored Programs (ORSP); and
   c. Notification of the Human Subjects Protection Office of FCOI management plans when the research involves human subjects.

   Reasonable efforts will be made to maintain the confidentiality of information disclosed and the Committee's deliberations, within the limits imposed by applicable laws and regulations.

2. **Notification of Research Sponsors:** The Associate Vice President for Research Administration and Finance will notify and provide initial and on-going FCOI reports to sponsors, including FCOIs of sub-recipient investigators or instances of non-compliance, in accordance with applicable sponsor regulations.

   For PHS FCOI reports, the timing and content of such reports will be consistent with 40 CFR 50.604-606.

H. Public Accessibility for PHS-funded Research: UConn Health will make information on FCOIs of PHS senior/key personnel publicly accessible upon request within five (5) business days after the request is received by the designated individual within the Office

of Audit, Compliance, and Ethics (OACE). Such disclosures shall be made in accordance with 42 CFR Part 50.605 (5)(i) and updated upon request.

I. Monitoring Compliance with the Policy and Mitigation: The Committee will monitor for compliance with this Policy.

1. **Failure to timely disclose an SFI:** The Committee or its designee will monitor to assure that SFIs are timely disclosed.

2. **Retrospective Review - Failure to timely disclose an SFI that is determined to be an FCOI and/or Failure to comply with a management plan:** If it is learned that a FCOI was not timely identified or managed, or if an investigator fails to comply with a FCOI management plan the Committee or its designee shall take the following actions:

    a. **PHS-funded Research:** Consistent with 42 CFR 50.605, a retrospective review shall be conducted and will cover key elements as specified by federal regulations, 40 CFR 50.605 (3) (B), and may result in updating the Individual Financial Disclosure Form, notifying the PHS and/or submitting/implementing a Mitigation Plan or other corrective actions, pursuant to 42 CFR 50.606.
    b. **Non-PHS Funded Research:** The committee may, in accordance with the sponsor's regulations or, if no sponsor regulations exist, at its discretion conduct retrospective reviews of non-PHS funded research.

3. **Enforcement:** UConn Health will comply with applicable sponsor's regulations regarding enforcement of this Policy.

J. Sanctions: Sanctions and penalties for those who knowingly and willfully disregard this policy, or refuse to comply with its terms, will be determined by the EVP in consultation with the Dean of the appropriate School with advice from the investigator's Department Head or Center Director. Sanctions include, but are not restricted to: letter of reprimand; reassignment of duties; adjustment of research space allocation; notification to professional and/or scientific societies, funding agencies and/or professional journals; termination of grant support; adjustment of salary; suspension or dismissal.

K. PHS Remedies: If the failure of an investigator to comply with this Policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of research, UConn Health shall promptly notify PHS of the corrective action taken or to be taken. Consistent with 42 CFR 50.606, PHS and/or the U.S. Department of Health and Human Services (HHS) may impose additional corrective or enforcement actions. In any case in which HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with a financial conflict of interest that was not managed or reported by UConn Health as required by 42 CFR 50 Subpart F, UConn Health shall require the investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

L. Maintenance of Records: The Committee or its designee shall maintain all records related to investigator disclosures of SFIs and related documentation and the Committee's review of and response to such disclosures (whether or not a disclosure resulted in the Committee's determination of a FCOI) and all actions under this Policy, or retrospective review, if applicable for at least three (3) years following the date the project terminates, the date the final expenditure report is submitted to the governmental sponsor or until the resolution of any federal action involving those records, whichever is longer.

M. Audits: In order to ensure that all disclosures are being made and identified financial conflicts managed, a relevant audit program will be implemented through the Office of Audit, Compliance and Ethics.

N. State of Connecticut Ethics for Public Officials: Connecticut General Statutes, Sec. 1-79 through 1-89, stipulates what types of activities are allowable for state employees who may have financial interests in companies which do business with the State of Connecticut. http://www.ethics.state.ct.us/. There are state regulations that deal with research activities. If investigators are doing research and receive any investment opportunities or payment directly from a company, the investigator needs to make sure that they are in compliance with the *State Code of Ethics*.

Frank M. Torti (Signed) 10/21/13

Frank M. Torti, M.D., M.P.H. **Date**
Executive Vice President for Health Affairs

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