

# **UConn HEALTH**

**POLICY NUMBER 2009-03**

**October 16, 2009**

**POLICY: Institutional Conflicts of Interest in Research**

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## PURPOSE:

The purpose of this policy is to outline an institutional approach for the identification and management of Institutional Conflicts of Interest (ICOI) in research, in a fashion that will foster both the conduct of scholarly activities including innovation, collaboration and technology transfer and ensure compliance with all Federal and State regulations.

This policy resides on the UConn Health website under “UConn Health Policies”. Hard copies are also available upon request by contacting the UConn Health Corporate Compliance Office. Material changes to the policy will be announced by Broadcast Message. Such changes will be accessible on the UConn Health website.

## POLICY STATEMENT:

This policy governs all Institutional Officials (IO) (see Definitions) with authority and/or responsibility for research programs, research administration, research funding or those officials in any other type of position with authority, direct or indirect, over the conduct of research.

As a fundamental principle, UConn Health will ensure that in practice, the functions and administrative responsibilities related to research are separated from those related to investment and technology licensing.

While this policy applies to all types of research at UConn Health, one essential goal is to protect the rights and safety of human subjects in our clinical trials.

Having an ICOI in research is not against UConn Health policy. However, steps must be taken to ensure that the ICOI can be and is managed.

There are two kinds of Institutional financial interests:

- The Institution
- Institutional Officials

The **Institution** may receive royalty income, gifts, and equity from for-profit and/or not-for-profit organizations.

**Institutional Officials** may influence decisions or be perceived to be able to influence decisions that may be of self-interest.

This ICOI Policy mandates that both of these types of financial interests, above certain thresholds, be reported.

For the purpose of this policy, an ***Institutional Conflict of Interest (ICOI in Research)***<sup>1</sup> means: an institution may have a conflict of interest in research whenever the financial interests of the institution, or of an **Institutional Official (IO)** acting within his or her authority on behalf of the institution, might affect – or reasonably appear to affect – institutional processes for the conduct, review, or oversight of research.

**Example 1:** A UConn Health IO is a member of the scientific advisory board for a company that sponsors research at UConn Health under the oversight of this IO.

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<sup>1</sup> “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research. A report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research. Association of American Medical Colleges (AAMC); Association of American Universities (AAU); February, 2008.

**Example 2:** A UConn Health IO owns stock in a company that is funding research at UConn Health, and this IO has oversight of general funds for research.

**Example 3:** The institution (UConn Health) owns stock in a company that is performing clinical trials at UConn Health with a new chemotherapeutic drug.

## Definitions:

**Blind Trust** means a trust that enables a person to avoid possible conflict of interest by transferring assets to a fiduciary; the person establishing the trust gives up the right to information about the assets.

**Bond** means a certificate of debt issued by a government or corporation guaranteeing payment of the original investment plus interest by a specified future date.

**Business** means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, Joint Stock Company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes.

**Clinical Investigation (DHHS Regulations 21 CFR 312)** means any experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects. An experiment here is any use of a drug except for the use of a marketed drug in the course of medical practice.

**Clinical investigation (FDA Regulations 21 CFR 50)** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter (FDA), regarding non-clinical laboratory studies.

**Commodities** mean articles of trade or commerce.

**Common stock** entitles the owner to a share of the corporation's profits and a share of the voting power in shareholder elections.

**Equity** means the common stock of a corporation.

**Human Subject (DHHS Regulations 45 CFR 46)** means a living individual about whom an investigator conducting research obtains:

- Data through intervention or interaction with the individual or
- Identifiable private information

**Human Subject (FDA regulations 21 CFR 50)** means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

**Immediate Family** means spouse, child, child's spouse, parent, brother, sister, dependent relative, any relative who is domiciled in the employee's household or unmarried partner who stands to gain financially by the employee's decisions.

**Individual Conflict of Interest (COI)** means a situation in which significant financial interests in a business, or other personal considerations provided by a business, may compromise, or have the

appearance of compromising, an investigator's professional judgment in conducting or reporting research, the results of which could affect the aforementioned business, either directly or indirectly. See [UConn Health Policy #2006-01 Individual Financial Conflicts of Interest in Research](#)

**Institutional Conflict of Interest (ICOI)** means: an institution may have a conflict of interest in research whenever the financial interests of the institution, or an Institutional Official (IO) acting within his or her authority on behalf of the institution, might affect – or reasonably appear to affect – institutional processes for the conduct, review, or oversight of research.

**Institutional Officials (IO)** include, but are not limited to, all University Officials with authority and/or responsibility for research administration or those officials in any other type of position with authority, direct or indirect, over the conduct of research. This excludes Principal Investigators (PIs). This includes, but is not limited to:

- Members of the ICOI in Research Committee;
- Vice President for Health Affairs;
- Dean of the School of Medicine;
- Dean of the School of Dental Medicine;
- Senior person responsible for Research Planning and Coordination;
- Senior person responsible for Clinical Research;
- Senior person responsible for Connecticut Institute of Clinical and Translational Science (CICATS);
- Senior person responsible for Research Administration and/or Finance;
- Department Chairs, Center Directors;
- Senior person responsible for the Human Subject Protection Office;
- Chairs and members of UConn Health Institutional Review Boards (IRB);
- Officials who participate in procurement or purchasing decisions with a commercial sponsor that conducts research at the institution;
- Officials from the Center for Science and Technology Commercialization;
- Officials with oversight of gifts and endowment monies from a sponsor that, by virtue of that authority, could affect review, conduct or oversight of research directly related to solicitation of the gift;
- Chairpersons/Committee Members who are empowered to make research-related decisions on behalf of the institution:
  - Data Safety Monitoring Boards (DSMB) with members employed by UConn Health;
  - Embryonic Stem Cell Research Oversight Committee (ESCRO);
  - Scientific Advisory Committees for the IRB.

**Investigator** means the principal investigator and any other person at UConn Health who is responsible for the design, conduct or reporting of research, and the investigator's **Immediate Family** (refer to definition). This shall include faculty and research staff (research associates and assistants), postdoctoral fellows, graduate students, visiting scientists, and medical or dental students engaged in research conducted in the department.

**Investigation (21 CFR 812)** means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

**Mutual Fund** means an investment company that continually offers new shares and buys existing shares back at the request of the shareholder and uses its capital to invest in diversified securities of other companies. Mutual Funds are not financial COIs.

**Options** mean a contract conveying a right to buy or sell designated securities, commodities, or property interest at a specified price during a stipulated period.

**Participate** means to be part of the described research activity in any capacity, including but not limited to serving as the principal investigator, co-investigator, research collaborator or provider of direct patient care. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis) or, in the case of clinical research, to the trial participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

**Research** (DHHS regulation 45 CFR 46) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**Securities** mean a document indicating ownership or creditorship; a stock certificate or bond.

**Significant Financial Interest** applying to **Institutions** includes one or more of the following:

- When an institution is entitled to receive royalties of any amount from the sale of the investigational product that is the subject of the research;
- When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a *non-publicly traded* sponsor of research at the institution;
- When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) of greater than \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a *publicly traded* sponsor of research at the institution;
- When an Institution accepts gifts of \$1 million or more for research from any for-profit organization or philanthropic unit associated with a for-profit organization.

**Significant Financial Interest** applying to **IO's** and their immediate families includes one or more of the following:

- Consulting income, value or potential value from stock shares, equity holdings, and royalties from a commercial sponsor of research conducted under the auspices of the institution of an amount exceeding \$10,000 of value or 5% ownership. Mutual funds are not included;
- An appointment to serve, in either a personal or representative capacity, as an officer, director, or board member of a commercial sponsor of research conducted at or under the auspices of the institution, whether or not remuneration is received for such services;
- An appointment to serve on the scientific advisory board of a commercial sponsor of research conducted at or under the auspices of the institution, unless the official has no current significant financial interest in the sponsor or the investigational product and agrees not to hold such an interest for a period of no less than three years following completion of any related research conducted at or under the auspices of the institution.

**Sponsor** (DHHS) means an individual company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial, but who does not actually conduct the investigation.

**Technology** means any compound, drug, device, diagnostic, medical, dental or surgical procedure intended for use in health care or health care delivery.

**Warrant** means a type of security issued by a corporation (usually together with a bond or preferred stock) that gives the holder the right to purchase a certain amount of common stock at a stated price.

## APPLICABLE GUIDELINES:

Several organizations and agencies are calling on all medical schools and major research universities to develop and implement institutional financial conflicts of interest policies within two years<sup>2</sup>. Our policy was written under the guidelines of the Office of Inspector General (OIG) for DHHS, National Institutes of Health (NIH), American Association of Medical Colleges (AAMC), and Association of American Universities (AAU). The web sites for these organizations and agencies are:

<http://oig.hhs.gov/oei/reports/oei-03-06-00460.pdf> U.S. Department of Health; Office of Inspector General

National Institutes of Health: Conflicts of Interest in Extramural Research; January 2008

[www.aamc.org](http://www.aamc.org) Association of American Medical Colleges (AAMC); February 2008

[www.aau.edu](http://www.aau.edu) Association of American Universities (AAU); February 2008

## KEY ELEMENTS OF THE POLICY:

1. A list of IOs who are required to complete ICOI forms is maintained by the Director of the Office of Research Compliance.
2. The COI in Research Management Committee is the committee used for **both Individual COI and Institutional COI**. Members will be appointed by the Vice President for Health Affairs, upon recommendation of the Deans of the Schools of Medicine and Dental Medicine, and the Director of the Office of Research Compliance.
3. The COI in Research Management Committee is composed of:
  - Five (5) senior faculty members, one of whom will be appointed as Chair; faculty members will serve terms of three years; the three year term may be extended by the Vice President of Health Affairs;
  - The Executive Director of The Center for Science and Technology Commercialization;
  - The Director of Human Subjects Protection Office (HSPO);
  - A Community-based person; community-based members will serve terms of three years; the three year term may be extended by the Vice President of Health Affairs;
  - The Senior Officer for Research Administration and Finance (*non-voting*);
  - Associate Vice President, Communications (*non voting*);
  - Director of the Office of Research Compliance (*non-voting*).
  - Member of Board of Directors
  - Provost or his/her designee

## PROCEDURES FOR IDENTIFYING AN ICOI:

**Conflicts Involving the Institution<sup>3</sup>:** Reportable financial conflicts are restricted to companies and corporate donors that could gain financially from outcomes of research performed at UConn Health. Senior staff members such as the Executive Director of the Center for Science and Technology Commercialization and the Chief Financial Officer and others who are responsible for all arrangements (e.g., technology license, gift, Institutional consulting agreement), worth more than \$100,000, must file annually (July 1<sup>st</sup>, and updated as necessary) an Annual Institutional COI Disclosure Form (Attachment 1)

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<sup>2</sup> The Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS), NIH, AAMC, AAU.

<sup>3</sup> Penn State University

to the COI in Research Management Committee and to the Vice President for Health Affairs. The report must have sufficient information (e.g., number of shares or percentage of ownership, amount of gift, magnitude and timing of payment, royalties) for a thorough review by the ICOI in Research Management Committee. Examples include:

- Equity holdings;
- Companies that hold option or licensing rights to UConn Health;
- Major corporate donors that exceed 1 million dollars;

IO(s) responsible for oversight of technology transfer activities shall report to the Director of the Office of Research Compliance when, as a result of a licensing agreement, the institution takes (or intends to take) an equity interest, stock options, or any entitlement to an ownership interest in, or royalty payments from, a potential sponsor of research in or under the auspices of the institution.

The COI in Research Management Committee will review the disclosures and develop conflict resolution plans to manage the conflict or minimize the potential for conflict of interest by reducing or eliminating the interest.

The Director of Research Compliance, acting on behalf of the COI in Research Management Committee will communicate with responsible IOs and committees as necessary; e.g. IRB, Institutional Animal Care and Use Committee (IACUC), a summary of the institutional financial interest. The dollar amounts will be held confidentially in the Office of Research Compliance.

Because of the complex nature of institutional conflicts of interest, the COI in Research Management Committee may, at its discretion, determine the necessity to appoint **an ad hoc review team** to:

- Understand the nature of the University Technology Transfer program proposed;
- Compile information about the financial interests involved and the various ways in which those interests might affect the proposed research project;
- Determine if there is in fact a “nesting” of potential conflicts of interest impacting a number of different University operations, e.g., research, services, intellectual property licensing, or purchasing of goods and services;
- Develop reasonable mechanisms for managing, reducing or eliminating institutional conflicts of interest.

After completing an analysis of an institutional conflict of interest, the ad hoc Review Team shall make a full report to the COI in Research Management Committee. The COI in Research Management Committee will, if necessary, design a management plan for the ICOI reviewed by the ad hoc Review Team, or eliminate the ICOI.

**Conflicts Involving Institutional Officials:** On July 1<sup>st</sup>, the Office of Research Compliance shall annually distribute Institutional Official COI Disclosure Forms (See Attachment 2) to IOs. The disclosure period is 12 months previous and 12 months post July 1<sup>st</sup>. The IOs are responsible for returning completed, signed and dated forms by October 1<sup>st</sup> to the Office of Research Compliance.

IO(s) are responsible for ensuring that an updated Institutional Official Financial Disclosure Form (Appendix 2) shall be completed and filed with the Office of Research Compliance at any time during the year when their significant financial interests or that of UConn Health may change.

From the ICOI Financial Disclosure Forms (Appendices 1 & 2), the Director of the Office of Research Compliance determines whether an ICOI may exist.

If an ICOI exists or appears to exist, the Director of the Office of Research Compliance will present the information to the COI in Research Management Committee. This committee will determine whether there

is an ICOI or the appearance of an ICOI, and will either design a management plan for the ICOI or eliminate the ICOI.

The COI in Research Management Committee determines whether the financial interest identified by IOs could affect decisions regarding, for example:

- Recruitment and/or treatment of human subjects in clinical trials;
- The design, conduct, or reporting of research;
- Promotion of research personnel;
- Financial gains for research personnel (such as increases in salary or funding of research); or
- Acquisition of laboratory space.

The Committee then determines what conditions or restrictions, if any, should be imposed by UConn Health to manage such conflicts. The COI in Research Management Committee may decide that the probability that potential harm from the conflict is too remote to warrant any specific conditions or restrictions, or alternatively, that the ICOI cannot be successfully managed. The Committee will be authorized to request any other information that it deems necessary to assist it in this determination.

Examples of conditions or restrictions that might be imposed on UConn Health and/or its IOs to manage or eliminate actual or potential ICOI in research include:

1. Public disclosure of significant financial interests of the Institution and/or its IOs;
2. Monitoring the decision-making of IOs when research is involved;
3. Monitoring the work and progress of graduate students;
4. Modification of the research;
5. Disqualification of the IO from participation in all or a portion of the activities that are the subject of the ICOI;
6. Creation of a blind trust;
7. Divestiture of the financial interests;
8. Severance of relationships that create actual or potential conflicts,
9. Use of an external Institutional Review Board.

The Committee will inform the HSPO of management plans for ICOI that involve human subjects in our clinical trials.

In the event that the COI in Research Management Committee is unable to resolve an identified ICOI, the research must be halted. The Director of the Office of Research Compliance will notify, in writing, the Associate Vice President of Research Administration and Finance, the Director of HSPO, Deans, the Vice President for Health Affairs and other appropriate persons as needed, with the facts surrounding the case. In the event that notification of research sponsors is required, the Director of the Office of Research Compliance will ensure that this notification occurs.

## **MAINTENANCE OF RECORDS:**

All records related to the implementation of this policy, e.g., Institution Financial Disclosure Reports, Institutional Officials Financial Disclosure Form, minutes from the meetings of the COI in Research Management Committee, notifications of IOs and funding agencies, etc., shall be securely maintained in the Office of Research Compliance. Research COI records must be retained for at least three years following termination of the research project.

ICOI management plans may be subject to periodic review for compliance with this policy by the Office of Audit, Compliance and Ethics and any agencies funding the research.



**APPEALS:**

In situations where an IO disputes the decision of the COI in Research Management Committee, the IO may present his/her case to the Committee. The Committee shall review the presentation for merit and will make a judgment. If further appeals are requested, an ad hoc committee will be formed by the Vice President for Health Affairs and the Provost.

**SANCTIONS:**

Sanctions and penalties for those who knowingly and willingly disregard this policy, or refuse to comply with its terms, will be determined by the Dean of the appropriate School, the Vice President for Health Affairs or Board of Directors as is appropriate. Sanctions include, but are not limited to:

- Letter of reprimand;
- Reassignment of duties;
- Adjustment of salary;
- Suspension;
- Dismissal.

**STATE OF CONNECTICUT:**

The **Code of Ethics for Public Officials**, Connecticut Statutes, Section 1-79 through 1-89 stipulate what types of activities are allowable for state employees who may have financial interests in companies that do business with the State of Connecticut. This Code of Ethics includes research and non-research activities. Questions about non-research activities should be directed to the University Ethics Liaison or the Office of State Ethics. <https://portal.ct.gov/ethics>

Cato T. Laurencin (signed)

11/10/09

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**Vice President for Health Affairs**

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**Date**

**NEW POLICY: 10/16/09**

**Approved by BoD 9/14/09**

**Appendix 1: Examples of Circumstances That May Create an *ICOI***

**Attachment 1: Annual Institutional COI Disclosure Form**

**Attachment 2: Annual Institutional Official COI Disclosure Form**

## Appendix 1

### **EXAMPLES OF CIRCUMSTANCES THAT MAY CREATE AN *ICOI*:**

UConn Health may hold equity or grant licenses. In these cases, the potential institutional conflicts become more likely for several reasons:<sup>4</sup>

1. Equity markets are not perfect. Speculators reacting to information such as research results may cause substantial changes in market value. This may occur before any product sales.
2. Owners of equity may cash in their shares prior to the product or service passing the market test of generating sales. This creates a situation where the institution and the inventor may enhance their positions relative to other shareholders by having superior or “insider” information.
3. The institution generally accepts a level of equity that could have substantial value if the product or service is successful. Therefore, the size of the transaction makes the potential institutional conflict even more serious.
4. The institution, as well as the inventor, must avoid even the appearance of manipulating stock prices through issuing or using information that may later prove incorrect, such as promoting a drug discovery that later fails FDA tests. Such manipulation exposes these entities and individuals to significant criminal and civil liabilities.

Situations in which conflicts may lead to decisions not in the best interest of UConn Health are:

1. In reporting the results to the public or in other public relations activities, the University and the investigator have an incentive to portray research progress and the potential for the company in the best possible light to maximize investor interest in the company.
2. If the research involves clinical trials sponsored by a company in which UConn Health holds an interest, there may be pressure on the institution and/or investigator to aggressively seek patients for these tests, to fail to inform patients of the potential conflict, and to ignore or minimize symptoms that suggest an adverse reaction to the drug or device.
3. The IO may inappropriately divert resources from research not funded by the licensee company (i.e.; supported by a federal agency or other corporate sponsor) to development of the invention.
4. The department may assign excessive laboratory space or other resources to the research project, to the detriment of other deserving projects.
5. The department, school, or University may have an incentive to keep the investigator on the faculty/staff and involved in the technology. This may conflict with normal tenure, promotion, and merit pay standards. For the same reason, the investigator may be allowed to enter into inappropriate consulting or other agreements with the company.
6. If another investigator at the institution invents an alternate therapy or product, which may be more efficacious for the patient or have more value for consumers, the University may not pursue further development or licensing because of economic competition with the existing invention.

However, acceptance of equity in licenses of University technologies is within the overall mission of UConn Health. There are two compelling reasons:

- Many technologies are best developed within a small entrepreneurial company. In such cases, cash held by these companies may be better employed in product development and marketing rather than paying a cash license fee.
- The development of technologies in a small company may enhance economic development within the region, which is also of benefit to UConn Health and the State of Connecticut. By licensing to new companies that locate within the region, jobs are created. If the company is successful, many jobs may be created.

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<sup>4</sup> Kansas University Medical School Institutional Conflict of Interest Policy; April 17, 2002