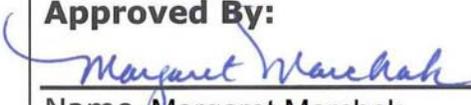


	Subject: Financial Conflict of Interest in Research	
Policy Level: I Policy Number: HHC-R01	Original Date: November 19, 1999 Revision Date(s) May 12, 2006 September 30, 2010 July 1, 2011 August 24, 2012 January 1, 2015	Approved By:  <hr/> David Haig VP, Chief Compliance Officer Approved By:  <hr/> Name Margaret Marchak Title SVP, Chief Legal Officer

Purpose:

The purpose of this policy is to define the process for identifying, evaluating, managing and reporting Investigators' Financial Interests that have, or may appear to have, an impact on the objectivity and integrity of Research conducted at Hartford HealthCare (HHC).

Scope:

This policy applies to all Investigators, regardless of title or position, who are **responsible** for the design, conduct or reporting of Research that is administered at HHC, regardless of funding source.

Policy:

It is HHC's policy to preserve the integrity and quality of Research at HHC and to maintain public trust in our scientific endeavors by managing actual or perceived conflicts of interest in the conduct of Research. Significant Financial Interests (SFI) may threaten scientific integrity, whether in appearance or in fact, regarding study design, review, data collection and analysis, adverse event reporting, or the presentation and publication of research findings. Therefore, all SFIs in regards to an Investigator's Institutional Responsibilities shall be disclosed, reviewed and managed in accordance with this policy.

Investigators identified with a SFI in research may not proceed with such Research until it has been determined whether a Financial Conflict of Interest (FCOI) exists and, if it does, a Management Plan is established and implemented.

Responsibilities:

Investigator

Investigators must disclose all Financial Interests during annual or updated disclosure submissions in accordance with this policy. It is the responsibility of the Principal Investigator or Project Director of a research project to ensure that each Investigator working on or who will work on the project submits a timely disclosure form.

Research Compliance Officer

The HHC Research Compliance Officer will administer the FCOI in Research process and coordinate the review of Financial Interest disclosures.

HHC Research Conflict of Interest Committee

The HHC Research Conflict of Interest Committee (RCOIC) will review, investigate, manage and provide oversight of Financial Interests determined to be FCOI in research at HHC.

Procedures:

Training

Prior to engaging in any research project, all Investigators must complete training on FCOI through the CITI training module. This training must be repeated at least every four (4) years and must be completed immediately:

- If this policy is revised to affect the requirements of Investigators,
- If an Investigator is new to HHC,
- Or if it is determined by HHC that an Investigator is found to have violated this policy or any applicable management plan.

Disclosure of Financial Interests

Each year, the HHC Research Compliance Officer will initiate the annual FCOI in Research process during the month of January.

All Investigators involved in animal or human subjects research must disclose and/or update Financial Interests related to his/her institutional responsibilities annually by completing the HHC *Financial Interests in Research Disclosure Form*. All disclosure forms must be completed and returned within 30 days of distribution.

Investigators also have the on-going responsibility to disclose the discovery or acquisition of new SFI to the HHC Research Compliance Officer within 30 days of the occurring event.

Review of Financial Interests Disclosure Forms

All forms are reviewed initially by the Research Compliance Officer.

All Investigators with forms indicating a SFI will be referred to the RCOIC for review.

Evaluation of Financial Conflicts of Interest

The RCOIC's principal objective is to ensure that Investigators and research staff do not engage in activities where the risk to research integrity and institutional reputation and fully support the responsible conduct of research according to laws, regulatory guidance and HHC policies.

When a potential FCOI is identified, the RCOIC will review and develop a management plan for the involved parties. Broadly, there is a process to apply a **rebuttable presumption** that either the financial interest should be eliminated, managed with RCOIC oversight or the Research should not be conducted at HHC. The presumption may be rebutted if the circumstances are deemed compelling by the RCOIC, and provided that the committee recommends an effective FCOI Management Plan.

Whether the presumption is successfully rebutted will depend upon an analysis of:

- the nature of the science,
- the nature of the overlapping interests,
- how closely the interest is tied to the research,
- the degree to which the interest may be affected by the research,
- the degree of risk that the research poses to human subjects and the integrity of the research, and
- the degree to which the FCOI can be effectively managed.

To the extent possible and reasonable under the circumstances, the RCOIC will work with Investigators to develop the means for the activity to take place while protecting the integrity of the research, the rights and welfare of the participants, and the reputation of the institution.

RCOIC members with potential conflicts, in fact or appearance, must abstain from the review and approval of potential FCOI and Management Plans.

In those cases where the RCOIC has determined that a FCOI exists, no research funds may be expended and no Research may begin or continue until the Investigator has agreed in writing to any Management Plan required by the RCOIC.

Management of Financial Conflicts of Interest

The RCOIC may approve of the activity if it is concluded that the potential for conflict is so remote or inconsequential that there is minimal probability for biasing the objectivity of the activity.

One or more of the following may be recommended to manage the conflict:

- Periodic peer review of the activity (oversight) by individuals that are independent of the Investigator, or external monitoring of the study.
- Divestiture of the financial or business interest
- Mitigation through an 'honest broker' position
- Modification of the protocol
- Assignment of a different Investigator without a financial or business conflict to control the activity
- Disclosure of the conflict in the human participant informed consent form
- Disclosure of the conflict when publishing the results of the study, in accordance with specific journal requirements, if applicable

The RCOIC notifies the Investigator of the nature of the conflict, and recommends a management plan to manage the conflict.

The recommendations of the RCOIC will be provided to the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC). The IRB or IACUC have the final authority to determine whether the Research will be approved with the FCOI and corresponding Management Plan, if any. Additional conditions for approval will be communicated to the Investigator by the IRB or IACUC as applicable.

Public Health Services (PHS) Funded Research Provisions

This section is applicable to all PHS funded Research with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS funded Research that is ongoing as of August 24, 2012, will become subject to this section as additional funds are

requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension.

1. SFI Disclosure

Each Investigator planning to participate in PHS-funded Research must disclose all SFI to the Research Compliance Officer:

- prior to submitting an application for PHS-funded Research;
- at least annually during the period of the award; and
- within 30 days of discovery or acquisition (e.g., through purchase, marriage, or inheritance) of new SFI.

2. Monitoring

In accordance with the PHS regulations, plans put into place to manage identified FCOI will be monitored for compliance until the completion of the PHS funded Research. Each management plan will specify the way in which that will be accomplished.

3. PHS Reporting Requirements

Grants and Contracts will submit FCOI reports to PHS under the following circumstances:

- Initial reports of FCOI must be made to PHS prior to expenditure of any funds provided under PHS funded Research. When identified conflicts of interest are eliminated before research funds are expended, HHC is not required to submit a report to PHS.
- At least annually, provide the status of the reported FCOI and any changes with the management plan at the same time progress reports are submitted, or at the time that an award is extended until the completion of the project.
- Within sixty (60) days of determining that a FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of ongoing PHS funded Research.
- Within sixty (60) days of determining that a FCOI exists for an Investigator who joins ongoing PHS funded Research.

4. Retrospective Review

When during the course of ongoing PHS funded Research, HHC identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the RCOIC will

review the SFI within sixty (60) days to determine whether it is related to PHS funded Research and whether a FCOI exists. If a FCOI is identified after such a review, a management plan will be implemented, at least on an interim basis. In addition, the RCOIC will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's research activities associated with the project to determine whether the Research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such Research. Documentation of the retrospective review will at minimum include key elements identified in the PHS regulations.

If the RCOIC determines in the conduct of its retrospective review of PHS funded Research that the Research or any part of it was biased, the RCOIC will recommend a mitigation plan to the Signatory Official and the appropriate department director to address any such issues. HHC will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.

5. Sub-recipient Requirements

If HHC carries out the PHS funded Research through a sub-recipient, HHC will incorporate as part of a written agreement with the sub-recipient terms that establish whether HHC's or the sub-recipient's policy on conflict of interest in research will apply to the sub-recipient Investigators.

If the sub-recipient's policy will apply, the sub-recipient will certify as part of the agreement that its policy complies with the PHS regulations. Additionally, the agreement shall specify time period(s) for the sub-recipient to report all identified financial conflicts of interest to HHC to enable HHC to provide timely reports to PHS.

If sub-recipients must comply with HHC's policy on conflict of interest, the agreement shall specify time period(s) for the sub-recipient to submit all sub-recipient Investigator disclosures of SFIs to HHC. Such time periods shall be sufficient to enable HHC to comply with timely review, management, and reporting obligations under the PHS regulations.

For purposes of this section, FCOI reports must be provided to PHS prior to the expenditure of funds and within 60 days of subsequently identified FCOI.

6. Public Accessibility Requirements

This policy will be made available on the HHC Research Administration and Office of Compliance, Audit and Privacy websites.

Public requests regarding information concerning identified FCOIs held by Senior/Key Personnel related to PHS-funded Research will be responded to within 5 business days of receipt by the HHC Research Compliance Officer. Disclosed information will include minimum key elements and be provided to the extent required by applicable PHS regulations.

FCOI information will remain available by HHC for 3 years from the date the information was most recently updated.

7. Non-compliance

If HHC determines that an Investigator fails to comply with this policy or a FCOI management plan which appears to have biased the design, conduct or reporting of Research, HHC will promptly notify PHS of the corrective action taken.

If the Department of Health and Human Services 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, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, HHC must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the Research and to request an addendum to previously published presentations.

Sanctions

Sanctions and penalties for those who knowingly and willfully disregard this policy, or refuse to comply with its terms, will be addressed in accordance with HHC policies and senior administration of HHC with guidance from the RCOIC.

Sanctions will include, but are not limited to:

- Letter of reprimand
- Termination of funding or grant support
- Notification to funding agencies and/or professional journals and societies

- Adjustment of research space allocation
- Suspension
- Dismissal

Records Retention

The HHC Research Compliance Officer will maintain all records related to the implementation of this policy, e.g., Financial Interest disclosure forms, electronic communications, and notifications to Investigators, funding agencies, etc. regardless of FCOI determination.

FCOI related records for externally funded research projects will be maintained for at least three (3) years from the date of submission of the final expenditures report (federally funded grants and cooperative agreements) or three years from the final payment (research contracts) or as otherwise required by law.

Definitions:

Entity - means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

Financial Conflict of Interest – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of Research.

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

Institutional Responsibilities - means an Investigator's professional responsibilities on behalf of Hartford HealthCare, which may include for example: activities such as Research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data Safety Monitoring Boards.

Investigator – means the Principal Investigator (PI) or Project Director (PD) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research administered at Hartford HealthCare.

Management Plan - means the action taken to address a financial conflict of interest, which includes reducing or eliminating the financial conflict of interest, to ensure that the design, conduct, and reporting of Research are free from bias or the appearance of bias.

Research - means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, 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). As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/Key Personnel - means the Principal Investigator (PI) or Project Director (PD) and any other person identified as senior/key personnel by Hartford HealthCare in the grant application, progress report, or any other report submitted by Hartford HealthCare, whether or not they receive salaries or compensation under the grant.

Significant Financial Interest – means 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:

- With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve (12) 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;
- With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- Any reimbursed or sponsored travel related to the Investigator's institutional responsibilities (i.e., travel is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available). This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The term *significant financial interest* does NOT include the following types of financial interests:

- salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- income from service on advisory committees or review panels for 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.

Related Policies:

HHC Conflict of Interest (Including Conflict of Commitment)