

Financial Conflict of Interest in Research

Prepared by: [Angelo Quaresima, CIA, CFE, CHRC](#)
Research Compliance Manager
Office of Compliance, Audit and Privacy

Governing Regulations & HHC Policies

PHS Regulations - 42 CFR Part 50 Subpart F - Promoting Objectivity in Research & 45 CFR Part 94 – Responsible Prospective Contractors

FDA Regulations – 21 CFR PART 54 - Financial Disclosure By Clinical Investigators

HHC System - Conflict of Interest Policy (including Conflict of Commitment)

HHC Research Program – Financial Conflicts of Interest in Research

Financial Conflict of Interest in Research

PURPOSE:

Financial Conflict of Interest (FCOI) in Research regulations and HHC policies promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial conflicts of interest.

The HHC FCOI in Research Policy applies a single conflict of interest standard to all Investigators regardless of funding source.

Key Definitions

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.

Examples include:

- Co-PIs
- Research Coordinators
- Research Assistants
- Nurses
- Consultants
- Pharmacy Technicians
- Data Entry Staff

Key Definitions

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Hartford HealthCare, which may include:

- Research
- Research Consultation
- Teaching
- Professional Practice
- Speaking Engagements
- Committee Membership, such as institutional review boards

Key Definitions, Cont'd

Significant Financial Interest (SFI) means one or more of the following financial interests of the Investigator and/or the Investigator's spouse or dependent children, that reasonably appears to be related to the Investigator's institutional responsibilities at HHC:

1. Any salary or payment for services (e.g., consulting fees, honoraria, paid authorship), and/or equity interest (e.g., stocks, stock options, other ownership interest) from a single **publicly** traded entity that, when aggregated, exceeds \$5,000
2. Any salary or payment for services (e.g., consulting fees, honoraria, paid authorship) from a **non-publicly** traded entity that exceeds \$5,000
3. Any equity interests (e.g., stocks, stock options, other ownership interest) in a **non-publicly** traded entity
4. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests
5. Any amount of reimbursed or sponsored travel

Key Definitions, Cont'd

SFI sources that Do Not require disclosure:

- Salary, royalties, or other remuneration from HHC
- Agreements to share in royalties related to intellectual property rights assigned to HHC
- Mutual funds and retirement accounts as long as the Investigator does not directly control the investment decisions
- Income from teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center or an academic research institute
- Income from service on committees or review panels for a federal, state, or local government agency, institution of higher education, an academic teaching hospital, a medical center, or an academic research institute
- Travel that is reimbursed or 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

Key Definitions, Cont'd

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

Remember: You are disclosing financial interests - NOT conflicts of interest.

Whether a conflict of interest exists is a determination based on the type and monetary value of financial interests you disclose, the nature of the research, your role in the research and other institutional responsibilities.

Training Requirements

Before engaging in research, each Investigator must complete the CITI FCOI training modules.

- Access and registration can be obtained through HHC Research Administration's webpage or www.citiprogram.org

Training must be repeated at least every four (4) years and must be completed immediately:

- If the FCOI in Research 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.

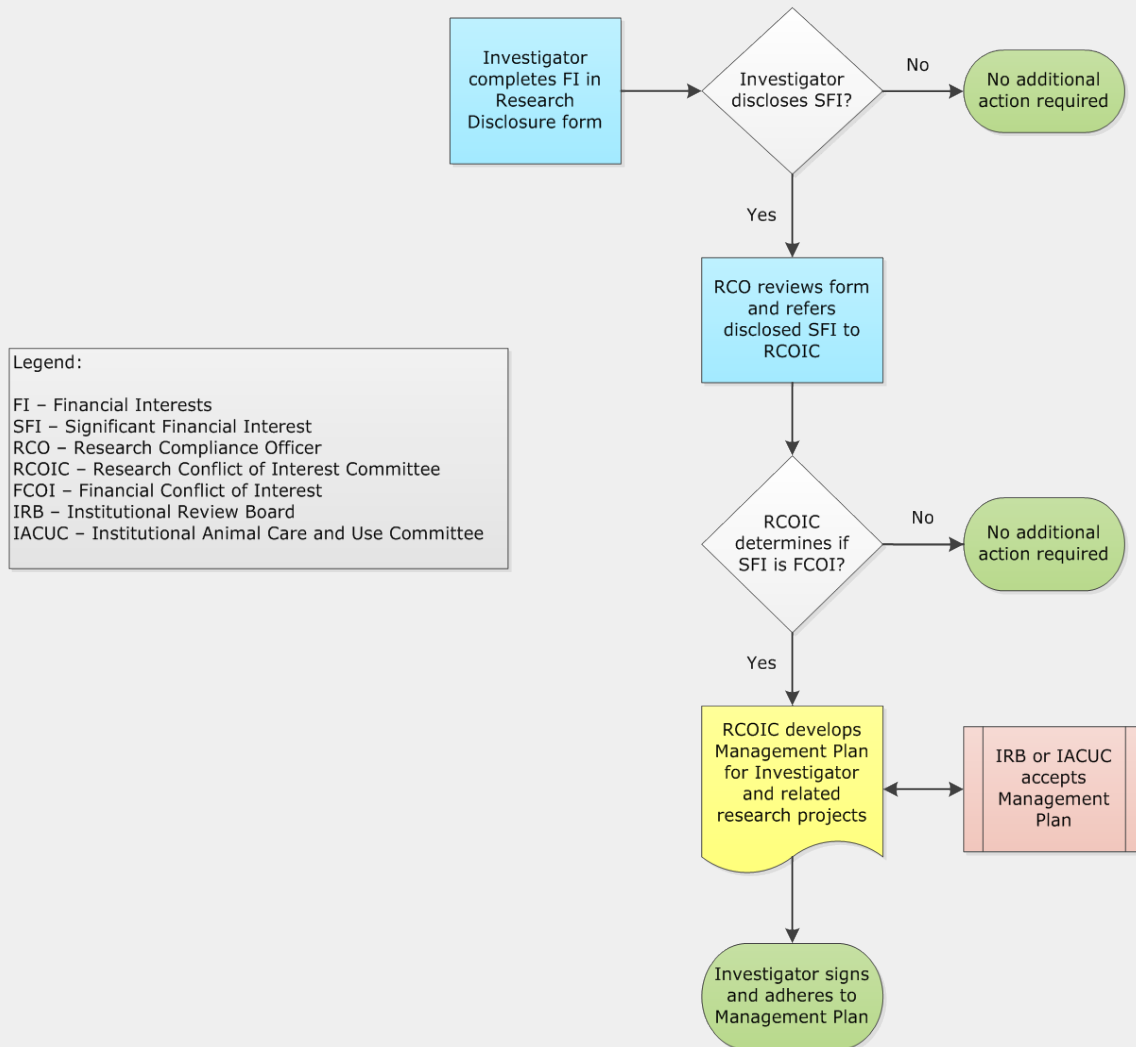
SFI Disclosure Process

- An **Investigator** must disclose all **SFI**:
 - 1) Annually during FCOI in Research process (each January)
 - 2) Within 30 days of discovery or acquisition of new SFI (e.g., through purchase, marriage, or inheritance)
- PD/PI is responsible to ensure each Investigator working on or who will work on the project submits a disclosure
- All disclosures are made through REDCap (Survey form)
- The HHC Research Compliance Officer will administer and conduct the initial review of all disclosures
- All identified SFI will be referred to the Research Conflict of Interest Committee (RCOIC) for evaluation and management

SFI Disclosure Process, Cont'd

- The RCOIC will develop a Management Plan (project specific) for all SFI determined to be FCOI
- The HHC IRB or IACUC have final authority to determine whether the research project will be approved with the FCOI and corresponding Management Plan
- Additional requirements apply to Public Health Service (PHS) funded projects:
 - Disclose all SFI prior to submitting an application
 - FCOI reporting to funding agency (Grants Administration)
 - Retrospective reviews/Mitigation plans
 - Sub-recipient
 - Public accessibility

SFI Disclosure Summary



Points to Remember

- Intent of disclosure is transparency and unbiased research!
- FCOI in Research process separate from HHC COI process
- Incomplete disclosures will delay SFI review and potentially delay approval of project by IRB/IACUC
- Investigator discloses SFI and RCOIC determines if FCOI exists
- The RCOIC develops management plans
- FCOI in Research Policy located on the HHC SharePoint webpage under Office of Compliance, Audit and Compliance and HH Research Administration webpage.

Contact Information

Angelo Quaresima, Research Compliance Manager,
860-972-7065 or angelo.quaresima@hhchealth.org

OCAP Main Line at 860-972-1573

Contact the ComplianceLine at **1-855-HHC-OCAP** or
HHC.OCAPComplianceLine.com

- Available 24/7/365
- Call/report anonymously

Working Together to do the Right Thing!