University of Connecticut Health Center
Guidance for Implementation of the
Individual Financial Conflicts of Interest in Research[1] Policy

http://www.policies.uchc.edu/policies/policy_2006_01.pdf

1. Responsible Institutional Office for this Policy: The Executive Vice President for Health Affairs is responsible for the implementation and enforcement of this Policy. The EVP has delegated authority to the *Individual Conflict of Interest in Research Management Committee* (the "Committee") and its designees for the solicitation, review and management of disclosures of significant financial interests.

2.Principal Investigator Responsibilities: Principal Investigators must identify at the time of proposal submission and award setup, those project personnel, including outside collaborators and/or consultants, who meet the definition of Investigators.[2]

---

1 Unless expressly required by the extramural funding agency's financial COI regulations, UCHC's policy excludes extramurally funded projects that are classified as instruction or "other sponsored activity" (e.g., public health service grants) when those projects do not incorporate a research purpose.

2 "Investigator" includes the Principal Investigator (PI) and any other person (regardless of title or position) that the PI identifies responsible for the design, conduct, or reporting of the research activity. This may include faculty and research staff as well as outside collaborating Investigators or consultants. Typically, Individuals who hold academic appointments (faculty) and sub-recipient investigators, collaborators or consultants with measurable effort are investigators when they have control over the design, conduct or reporting of the research. This policy does not apply to employees (e.g., research assistants, technicians, etc.) or graduate students who work directly under the supervision of an Investigator unless the Principal Investigator has identified those individuals as being *responsible* for the design, conduct or reporting of the research.

Research Activity: means any grant or contract processed by the Office of Research and Sponsored Programs that is classified as research or any activity that is subject to 45 CFR 46. This policy excludes projects that are educational/instructional, public service or other sponsored activity, unless those activities also incorporate a research purpose.

Design: means developing or planning the research strategy/method to be used in the project. Research designs address specific scientific hypotheses and identify which questions to study and how.

Conduct: means the supervision/management of the execution of the research project. Typically the responsibility of the Principal Investigator and co-investigators, it may also be performed by postdoctoral fellows or other personnel who have significant independence or supervisory responsibility for subordinate project personnel.
For studies involving human subjects, conduct also means anyone who is responsible for explaining the project, risk-benefits, or alternatives and/or obtaining consent from study participants and/or who must complete a sponsor's conflict of interest form.

Reporting: means the authorship of publications, manuscripts or reports; this includes anyone who will likely present the research results at scientific meetings.

In the event of a dispute, the final determination of who serves as an Investigator shall be made by the Associate Vice President of Research Administration and Finance, who will take into consideration the individual's function, role and degree of independence exercised while participating in the research project.

3. Investigator Responsibilities: All Investigators have a duty to:

- Disclose any significant financial interests (SFIs) reasonably related to their Institutional Responsibilities, including any SFIs of a spouse or dependent child;
- Cooperate fully with the Committee and, if applicable,
- Comply with FCOI management plans and training requirements, in accordance with this Policy.

4. Disclosure of Significant Financial Interests[3]:

3 Full, written disclosure of all Significant Financial Interests (including SFIs of an Investigator's spouse or dependent children) means:

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**; or

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 child) 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.

In addition, for research covered by **FDA regulations,** financial arrangements that must also be disclosed include:

a. Compensation made to the Investigator in which the value of compensation could be affected by the outcome of the study/research project.
b. A proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement.
c. 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 investigator's 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 1 year following completion of the study.

Travel: PHS funded Investigators must disclose all travel reimbursements that are either sponsored (that is paid for by an outside entity) or reimbursed directly to the Investigator from an outside entity for travel that occurs after August 24, 2012 that is related to the Investigator's Institutional Responsibilities, however, this disclosure requirement does ***not*** apply to sponsored or reimbursed travel by UCHC (for example as part of sponsored research projects, paid from departmental discretionary or gift funds) or from an institution of higher education, a federal/state/local government, an academic teaching hospital, a medical center, or a research institution affiliated with an institution of higher education.

Disclosure forms can be found here:
http://orc.uchc.edu/forms/pdfs/individual_financial_disclosure_research_form.pdf

Submit/return completed disclosure forms to: Gustavo Fernandez at: gfernandez@nso2.uchc.edu

- **Annual Disclosure:** Disclosure of any reportable SFIs shall be made annually. The Committee or its designee distributes the *Individual Financial Disclosure Form* to UCHC Department Administrators in the Schools of Medicine and Dental Medicine for distribution to all Investigators engaged in research conducted in the department. Annual distribution of disclosure forms occurs in January/March for the previous January 1 – December 31 calendar year. Department Administrators are responsible for assuring that completed forms are returned to the Committee or its designee.

- **Changes:** An updated disclosure form must be completed and filed within thirty (30) days of the acquisition or discovery of a reportable SFI.[4]

- **Submission of Institutional Review Board Protocols (Human Subject Research):** Investigators, coordinators and persons obtaining consent must 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 UCHC Human Subject Protection Office (HSPO) policies http://hspo.uchc.edu/Policies/2011-012.0.pdf , 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.

5. Public Health Services (PHS): PHS-funded research activities are subject to additional PHS requirements.

A. Awards Governed by PHS Conflict of Interest Regulations:

1. PHS Agencies:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

4 This includes whenever a previously disclosed financial interest that was below the $5K threshold meets or exceeds $5K, either for the Investigator or in aggregate (this combined with the financial interest of a spouse and/or dependent child).

- National Institutes of Health (NIH)*
  *NIH comprises 27 separate institutes and includes offices and centers, which fund research (http://www.nih.gov/icd):
- National Cancer Institute (NCI)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Library of Medicine (NLM)
- National Institute of Child Health and Human Development (NICHD)
- National Institute of General Medical Sciences (NIGMS)
- National Eye Institute (NEI)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute on Drug Abuse (NIDA)
- National Institute on Aging (NIA)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Nursing Research (NINR)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Human Genome Research Institute (NHGRI)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Institute on Minority Health and Health Disparities (NIMHD)

2. Other Sponsors that have requested UCHC adopt the PHS Standard for review of financial conflicts of interest:

- American Cancer Society
- American Heart Association

B. Training and Travel requirements applying to Investigators:

1. **Training Requirements: All investigators** must complete training prior to engaging in research and at least every four (4) years, as well as immediately under the following circumstances (immediately is defined as the timeframes noted in parentheses):

   a. An Investigator is new to UCHC (prior to engaging in research);
   b. UCHC finds that an Investigator is not in compliance with UCHC's Financial Conflict of Interest policy or management plan, as applicable (within 60 days); or
   c. UCHC Financial Conflict of Interest policies change in a manner that affects Investigator requirements (within 60 days).

   To complete Financial Conflict of Interest of Training: http://saba.uchc.edu If you are not a UCHC employee please review the UCHC PHS Conflict of Interest Training Module and return the certification of training form to: ORSP@uchc.edu.

2. **Additional PHS Disclosures/Reporting Requirements:** PHS Investigators must disclose all SFIs prior to engaging in PHS-funded Research.

   a. **Travel:** a Significant Financial Interest (SFI) includes *any* Reimbursed or Sponsored Travel, regardless of amount, provided to a PHS Investigator by an outside entity on or after August 24, 2012. This disclosure requirement does ***not*** apply to travel reimbursements to the PHS Investigator by UCHC (for example as part of sponsored research projects, paid from departmental discretionary or gift funds).

   b. **Changes in SFI:** For existing PHS awards, new or newly identified SFIs will be reviewed within sixty (60) days to determine if an FCOI exists and, if so, UCHC will implement an interim management plan or other measures to ensure objectivity of the research. Additionally, UCHC will report newly identified FCOIs to the applicable PHS agency within sixty (60) days of identification, as required by PHS regulations.

   c. **Certification and Disclosure with each PHS Application Submission:** At the time of submission of a proposal or progress report to PHS, an Investigator must certify that he or she has disclosed all SFIs (and those of his/her spouse and dependent children) that would reasonably appear to be related to the Investigator's Institutional Responsibilities. The PHS Investigator's signature on the ORSP Routing Form acts as certification and assurance that the Investigator is in compliance with this Policy.

d. **New Investigators:** If PHS-funded research is ongoing and an Investigator newly participating in the project discloses an SFI related to that research, those SFIs will be reviewed within sixty (60) days to determine if an FCOI exists and, if so, UCHC will implement an interim management plan or other measures to ensure objectivity of the research.

6. Individual Conflict of Interest in Research Management Committee – Review, Determination, Management

A. The ***Individual COI in Research Management Committee*** (i.e., Committee) is composed of at least five (5) senior faculty, one of whom is appointed as chair, and one community member. Responsible efforts are made to have representation on this committee of faculty who have experience in industrially sponsored research, as well as basic and clinical research. A compliance representative serves as an ex-officio member of the Committee.

B. A **review** of financial disclosures involves:

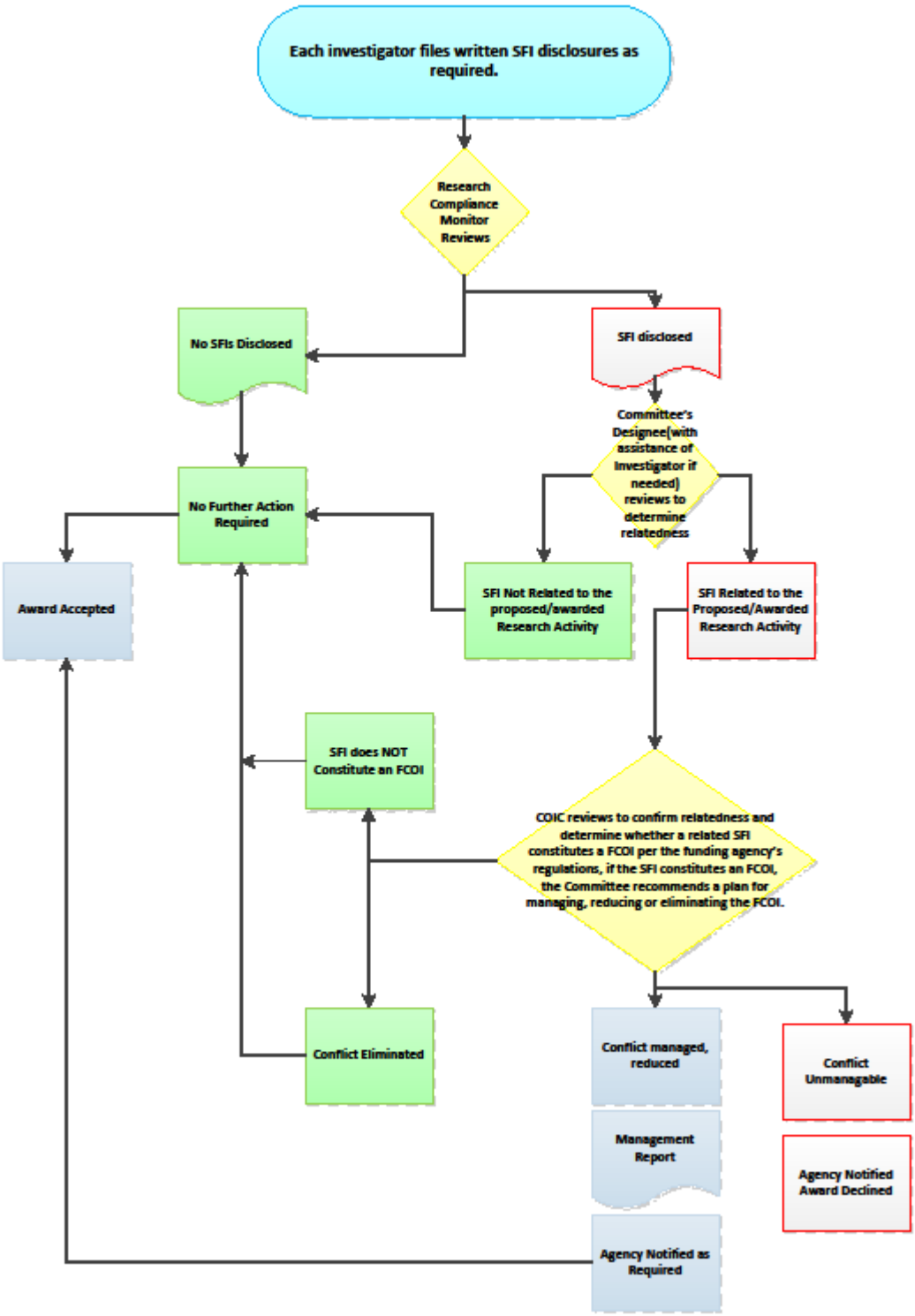
1. Investigator discloses SFIs reasonably related to his or her Institutional Responsibilities.

2. The Committee or its designee[5] determines whether the SFI is related to the proposed research project.

3. If the SFI is related to the research activity, the Committee determines whether the related SFI constitutes an FCOI.

4. If there is an FCOI, the Committee will recommend a management plan to manage, reduce or eliminate the FCOI.

5 The Committee or its designee may work directly with the Investigator and/or Department Chair and Dean to determine whether the SFI is related to the proposed research.


Each investigator files written SFI disclosures as required.
Research Compliance Monitor Reviews
No SFIs Disclosed
SFI disclosed
Committee's Designee(with assistance of investigator if needed) reviews to determine relatedness
No Further Action Required
Award Accepted
SFI Not Related to the proposed/awarded Research Activity
SFI Related to the Proposed/Awarded Research Activity
SFI does NOT Constitute an FCOI
COIC reviews to confirm relatedness and determine whether a related SFI constitutes a FCOI per the funding agency's regulations, if the SFI constitutes an FCOI, the Committee recommends a plan for managing, reducing or eliminating the FCOI.
Conflict Eliminated
Conflict managed, reduced
Conflict Unmanagable
Management Report
Agency Notified Award Declined
Agency Notified as Required

C. Determinations:

1. **Determination of Relatedness:** An Investigator's Significant Financial Interest is related to the proposed research when the Committee reasonably determines that the SFI:
   a. could be affected by the research; or
   b. is in an entity whose financial interest could be affected by the research.

2. **Determination of a Financial Conflict of Interest:** A financial conflict of interest (FCOI) exists when the Committee reasonably determines that the SFI is related to the research (as described under #1 above) ***and*** could directly ***and*** significantly affect the design, conduct, or reporting of the research.

D. Management Plans: Examples of conditions or restrictions that might be imposed to manage, mitigate, or eliminate identified FCOIs include:

1. Public disclosure of significant financial interests (e.g., disclosure on manuscripts submitted for publication, on abstracts and posters submitted for presentation; and, if human subjects involved, directly to participants);
2. Monitoring of the individual and/or their work by independent reviewers;
3. Modification of the research;
4. Disqualification from participation in all or a portion of the activities that would be affected by the FCOI;
5. Divestiture or reduction of the financial interests; or,
6. Severance of relationships that create actual or potential conflicts.

The Investigator is required to sign and comply with the written management plan.

E. Reconsideration/Appeals: Investigators may request that the Committee reconsider its determinations and, if denied, appeal the Committee's determination to the EVP of Health Affairs, in accordance with this Policy. The decision of the EVP is final and binding.

The following, brief examples of FCOIs are provided for illustrative purposes only. Recommendations for the effective management of FCOIs are very fact-dependent.

Case 1: The Investigator has an on-going consulting arrangement or modest (e.g., $5K) significant financial interest in a company sponsoring the research project. *The Committee may require that Investigator disclose these interests in presentations and publications.*

Case 2: The Investigator's spouse holds a position with the company sponsoring the research: *If the Investigator's spouse manages the research or commercial/financial direction of the company, the committee will assess a number of factors, for example: the degree of control the spouse has over the proposed research, what if any restrictions the sponsor has imposed on the conduct of the research, publication of research results or future intellectual property; the nexus between the sponsor's commercial interests and the proposed research, etc. Depending on weight of each factor, in addition to public disclosure of the FCOI, the committee may*

recommend that an ad hoc oversight faculty committee monitor the research project or require other safeguards.

Case 3: A faculty member has a financial interest in a company she founded. That company has received a PHS award (not Phase I SBIR/STTR), that included a consortium arrangement with the University (her research lab). As the company's research director, the Investigator has complete control over the scientific management of the company and influence over the company's finances. *Under this scenario, it is unlikely that public disclosures of the conflicting financial interests or monitoring will be sufficient to ensure that the research undertaken by the Investigator in her capacity as a University researcher will provide sufficient safeguards to protect the research from potential of bias. Accordingly, the Committee may recommend that the University's sub-award be reviewed and if the design does not appear to have been biased by the financial conflict of interest have the research conducted by an independent Investigator or, if no experienced Investigator without financial conflict is available, decline the sub-award.*

7. **Public Accessibility of FCOIs:** UCHC will disclose upon request, FCOIs held by PHS senior/key personnel; such disclosures will be in writing and include the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest in dollar ranges or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. UCHC will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the UCHC's identification of a new FCOI, which should be requested subsequently by the requestor. FCOI information shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

8. **Sub-recipient Investigators:** If a sub-recipient Investigator carries out a portion of the work, the AVP of Research Administration and Finance (or designee) shall take reasonable steps to ensure that any sub-recipient Investigator complies with the sponsor's FCOI regulations. For PHS research, if the sub-recipient's Institution lacks a PHS-compliant policy, the sub-recipient Investigator (including collaborators or consultants who meet the definition of Investigator) will be subject to UCHC's policy.

9. **Non-Compliance:** Instances of Non-Compliance include:
   - Failure to submit a required disclosure report;
   - Incomplete, erroneous, misleading or false disclosures;
   - Failure to provide additional information as requested by the Committee or its designee;
   - Failure to comply with the management or mitigation plans.

   Non-compliance may subject an Investigator to disciplinary action and/or sanctions.

10. PHS Monitoring/Corrective Actions: the Committee will take appropriate action to ensure effective review and management of SFI/FCOIs and compliance with this Policy:

1. If it is learned that a significant financial interest (SFI) was not timely disclosed or was not timely reviewed, the Committee shall, not later than the sixtieth (60th) day after learning of the interest, complete the following:

- determine whether the SFI is an FCOI; and
- if an FCOI exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.

2. If it is learned that an FCOI was not timely identified or managed, or if an Investigator fails to comply with a management plan, the Committee shall, not later than the 120th day after determining noncompliance:

- complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and
- implement any measures necessary with regard to the Investigator's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.

11. Additional Remedies for Non-Compliance (PHS-funded research):

A. Bias: PHS regulations require UCHC to notify the PHS of instances in which the failure of an Investigator to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require UCHC to take action appropriate to maintaining objectivity in the research. Sanctions may be imposed by UCHC or PHS as appropriate.

B. Clinical research: If the HHS determines clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by UCHC as required by federal regulation, UCHC will require the covered Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Contacts, Forms, and Additional Resources

Individual Financial Conflicts of Interest in Research Policy:
http://www.policies.uchc.edu/policies/policy_2006_01.pdf

Compliance Hotline: The UConn Health Center welcomes the reporting of compliance concerns. If you would like to remain completely anonymous, you may call **REPORTLINE at 1-888-685-2637**, a confidential service operated by a private (non-UConn Health Center) company, which forwards information to the compliance office.

Training:

- UCHC online training can be accessed here: http://saba.uchc.edu
- Training Module (with Investigator Certification Form) can be accessed via: http://orsp.uchc.edu/forms/index.html

Forms:

- UCHC Financial Disclosure Form
  http://orc.uchc.edu/forms/pdfs/individual_financial_disclosure_research_form.pdf

- UCHC ORSP Review, Certification & Approval (internal routing) and Sub-Recipient Statement of Intent forms can be accessed via http://orsp.uchc.edu/forms

Related Policies & Regulations:

- ***University of Connecticut***

  o Faculty Consulting policies:
  http://www.policies.uchc.edu/policies/policy_2000_01.pdf
  http://consulting.uconn.edu/documents/faculty_consulting_policy_04_13_2011.pdf

- ***University of Connecticut Health Center***

  o Institutional Conflict of Interest in Research Policy
  http://www.policies.uchc.edu/policies/policy_2009_03.pdf
  http://www.policies.uchc.edu/policies/policy_2009_03_form1.pdf
  http://www.policies.uchc.edu/policies/policy_2009_03_form2.pdf
- ***State of Connecticut***

  o State Code of Ethics
  o Connecticut General Laws §1-85

- ***Federal***

  - 42 CFR 50, Subpart F: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and 45 C.F.R. Part 94, Responsible Prospective Contractors

  - NIH OER: http://www.grants.nih.gov/grants/policy/coi/nih_review.htm

  - NOT-OD-05-013: http://grants.nih.gov/grants/guide/notice-files/not-od-05-013.html

  - NIH Resources (including FDA): http://grants.nih.gov/grants/policy/coi/resources.htm

  - Food and Drug Administration: Financial Disclosure by Clinical Investigators; http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf

  - NSF: NSF Grant Policy Manual: 501 Conflict of Interest Policies