FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATION revisions For PHS funded Researchers
(effective 8/24/12)

Significant Financial Interest (SFI) means a financial interest or income received or held by an Investigator, his or her spouse, or dependent children that reasonably appears to be related to the Investigator's institutional responsibilities.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

An Investigator is the principal investigator and any co-principal investigators for a research project. This includes, but is not limited to, the project director, principal investigator, or 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.

Remuneration: non-salary payments, i.e. consulting fees, honoraria, paid authorship

Equity Interest: stock, stock option, or other ownership interest

Examples of SFI that must be disclosed are:

1. Interest or income in or from a **publicly traded** entity where
   - the aggregate value of Remuneration and any equity interest exceeds $5000 (any remuneration received during the 12 month period preceding the disclosure; the value of any equity interests in the entity as of the date of disclosure)
   - the entity is sponsoring any of the Investigator’s research;

2. Interest or income in or from a **non-publicly traded** entity where the aggregate value of remuneration exceeds $5000 (any remuneration received during the 12 month period preceding the disclosure) **or** when any equity Interests are held

3. Interest in the form of income related to intellectual property rights and interests paid by an entity other than Northeastern University

4. Travel related to Institutional responsibilities not reimbursed or sponsored by Northeastern University, including but not limited to travel sponsored by international universities, corporate sponsors, foundations e.g. American Cancer Society, American Heart Association, etc.
   - Travel disclosure must include at a minimum, the purpose of the trip, the identity of the organization or entity funding the travel, the destination, and the duration of the trip (usually days).

5. Phase II SBIR/STTR applications

Significant Financial Interest does NOT include:

1. Remuneration or Royalties paid by Northeastern University to the Investigator;
2. Remuneration from authorship of academic or scholarly works;
3. Remuneration and sponsored/reimbursed travel related to seminars, lectures, or teaching engagements sponsored by, or from advisory committees or review panels for, U.S. Federal, state, or local governmental agencies; U.S. institutes of higher education; U.S. research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers;
4. Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions for these vehicles.

5. Phase I SBIR/STTR applications
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Investigators must disclose Significant Financial Interest (SFI)...

1. **Annually.** Investigators must disclose their Significant Financial Interests to Northeastern University on an annual basis via COEUS, and must disclose certain information with respect to conflicts of commitment and interest as prescribed in the Faculty Handbook.

2. **Proposal-related Disclosures.** Prior to submitting a proposal for funding, the Principal Investigators identified in the proposal and, if requested by the Institutional Official or the Designated Official, other Investigators associated with the proposal must disclose whether the Investigator's Significant Financial Interests may be related by the proposal. If there is a potential relationship, the Investigator must file a full disclosure with additional information regarding the relationship of the project to the Related Company prior to submission of the proposal to the sponsor.

3. **Ad hoc Disclosures.**
   1. An Investigator must disclose via COEUS on an ad hoc basis any new Significant Financial Interest within 30 days following the date on which the Significant Financial Interest is acquired or arises. This 30 day requirement is specific to the PHS regulations.
   2. An Investigator must disclose COEUS on an ad hoc basis his or her Significant Financial Interests prior to the Investigator commencing participation in an existing research project.

Investigator Training is required...

- Prior to engaging in research related to any PHS-funded grant and at least every four years
- Immediately when any of the following circumstances apply:
  - The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of PHS funded Investigators;
  - A PHS funded Investigator is new to an Institution; or
  - An Institution finds that a PHS funded Investigator is not in compliance with the Institutions financial conflict of interest policy or management plan.

Institutions must develop and implement a management plan if FCOI is identified in PHS funded research

- Management plan must include specific actions that will be taken to eliminate or manage the Financial Conflict of Interest so as to mitigate the effect of the bias.
- If the Financial Conflict of Interest arises during the term of the award, Institutions must notify PHS of the FCOI and management plan within 60 days following the Investigator's disclosure of the Significant Financial Interest
- If an Institution failed to manage an FCOI or a researcher failed to comply with a management plan, a retrospective review must be conducted to determine if bias existed during the period of non-compliance. If bias is identified, Institutions must notify PHS promptly and submit a mitigation report. The mitigation report must include, at a minimum:
  - The elements documented in the retrospective review
  - A description of the impact of the bias on the research; and
  - The Institutions plan of action or the actions taken to eliminate or mitigate the effect of the bias (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm; etc.).