



# EMMANUEL COLLEGE

## Office of Sponsored Programs

### **Financial Conflict of Interest (FCOI) Policy**

#### **Introduction**

As a liberal arts and sciences college in the Catholic tradition, Emmanuel College has a responsibility to ensure that our teaching and research environment fosters the generation of new knowledge and positive learning opportunities for our students and preserves the integrity of our research enterprise.

An investigator's financial interest in a company or other organization (or that of his or her immediate family) may produce a real or perceived financial conflict of interest that could directly and significantly affect the design, conduct or reporting of research. In accordance with federal regulations, Emmanuel College has the responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a significant financial interest of an investigator. Federal regulations require institutions to have policies and procedures in place to ensure that investigators disclose any significant financial interests: as part of annual reporting processes; as these occur in real time; and prior to proposal submission.

#### **Conflict of Interest**

A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the College such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain - financial or otherwise. To say that one has a conflict of interest does not necessarily mean that the individual has acted or is expected to act inappropriately. It is the existence of the competing interests that creates the initial conflict of interest concern.

- *Annual Disclosure and Certification Process: Emmanuel College requires that all faculty members file an annual Report on Outside Professional Activities at the beginning of fall term: (1) to report on compensated outside professional activity and uncompensated outside professional activity and (2) to disclose significant financial interests. The annual disclosure and certification process, which occurs during fall term, is conducted by the Office of Human Resources on behalf of the Vice President of Academic Affairs.*

#### **Financial Conflict of Interest (FCOI)**

The federal government established new regulations for defining, disclosing and reporting on significant financial interests (SFI). These became effective on 24 August 2012 and they expand



## Office of Sponsored Programs

upon previous conflict of interest regulations established in 1995. A financial conflict of interest (FCOI) is one where the College reasonably determines that the significant financial interest of an investigator could directly and significantly affect the design, conduct or reporting of research. Significant financial interests, or any employment or consulting roles, raise particular questions of potential or apparent financial conflicts of interest which require special ad hoc disclosures, review and approval. In addition to filing an annual disclosure and certification in the fall – as noted in the preceding section, faculty must also disclose significant financial interests in the following ways:

- *Ad hoc Disclosure Process: Outside of the annual reporting process, any new significant financial interest must be disclosed within 30 days following the date on which the significant financial interest is acquired or arises. This disclosure must be made to the Department Chair, who will inform the College's Chief Research Compliance Officer.*
- *Proposal-related Disclosure Process: Prior to submitting a proposal for funding, the investigators identified in the proposal must disclose whether they have significant financial interests that may be related to 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. This disclosure must be made to the Department Chair, who will inform the College's Chief Research Compliance Officer. Some sponsors – most notably the Public Health Service (PHS) – require mandatory FCOI training for the investigator prior to beginning work on a sponsored project.*

### FAQs

#### **Q: What is considered a significant financial interest (SFI)?**

A: A significant financial interest means a financial interest or income received or held by an investigator - alone or in combination with his or her family - that reasonably appears to be related to the PI's institutional responsibilities.

#### **Q: What are some examples of significant financial interests (SFIs)?**

A: Examples of SFIs include:

1. Interest in or income from a publicly-traded entity where
  - a. the aggregate value of remuneration and any equity interest exceeds \$5,000 (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)
  - b. the entity is sponsoring any of the investigator's research



## Office of Sponsored Programs

2. Income from a non-publicly-traded entity where the aggregate value of remuneration exceeds \$5,000 (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 Emmanuel College
4. Travel related to institutional responsibilities not reimbursed or sponsored by Emmanuel College, including – but not limited to – travel sponsored by international universities, corporate sponsors, and foundations

*The revised PHS fCOI regulations now include a requirement for **Investigators** on PHS projects to disclose the occurrence of travel paid by outside entities (where the aggregate of significant financial interests and travel reimbursements from the single entity exceeds \$5,000 in the previous twelve months). Any **Investigator** receiving PHS funding must disclose to their Dean or designee the occurrence of any reimbursed or sponsored travel (i.e., that which is paid by a third party directly to or on behalf of the **Investigator** so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, a U.S.-based 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.*

5. Applications for grants for Phase II Small Business Administration (SBA) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTT) funding

**Q: What are some examples of what is NOT considered significant financial interests (SFIs)?**

A: Examples of what would not be considered SFIs include:

1. Remuneration or royalties paid by Emmanuel College to the investigator
2. Remuneration from authorship of academic or scholarly work
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. institutions of higher education; U.S. research institutions affiliated with institutions 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. Applications for grants for Phase I Small Business Administration (SBA) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (SBTT) funding

**Q: What is the “PHS Rule”?**



## Office of Sponsored Programs

A: Since 1995, the federal government has regulated issues of financial conflict of interest in federally-funded research. On May 21, 2010, in response to criticism from the Office of Inspector General of the Department of Health and Human Services (DHHS) of compliance, DHHS proposed substantial modifications to the 1995 regulation affecting institutions seeking and/or receiving Public Health Service (“PHS”) funds. These changes were finalized in August 2011 and went into effect on August 24, 2012. The PHS Rule is available online: [Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought](#) (42 CFR 50 Subpart F).

**Q: Does the PHS Rule extend to subrecipients?**

A: Yes. The regulation is applicable to each Institution that applies for PHS grants or cooperative agreements for research or submits a proposal for a research contract whether in response to a solicitation or otherwise and, through the implementation of the regulation by each Institution, to each Investigator participating in such research.

**Q: How do I find FCOI training?**

A: FCOI training is available via the CITI (Collaborative Institutional Training Initiative) program, to which Emmanuel College subscribes for our research compliance training needs. To take FCOI training, please go to the CITI website at [www.citiprogram.org](http://www.citiprogram.org) and click on the Responsible Conduct of Research course. The Financial Conflict of Interest modules are part of the Conflict of Interest section. The first two modules - “Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules” and “Institutional Responsibilities as They Affect Investigators” - comprise the FCOI training requirement.

**Q: Is FCOI training required for faculty engaged in research?**

A: FCOI training is required for investigators with funding from the U.S. Public Service (PHS) and must be completed prior to beginning work on a PHS-funded project. The National Institutes of Health (NIH) are under the aegis of the PHS. For all other sponsors, OSP will inform the investigator whether training is required as a condition of the award.

FCOI training is recommended for all faculty engaged in research, regardless of funding source.

FCOI training is open to all members of the Emmanuel community and is encouraged for those with an interest in this topic.

### **Important Links**

U.S. Public Health Service (PHS): <http://grants.nih.gov/grants/policy/coi/>

National Science Foundation (NSF):  
[http://www.nsf.gov/pubs/policydocs/pappguide/nsf08\\_1/aag\\_4.jsp](http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/aag_4.jsp)



# EMMANUEL COLLEGE

Office of Sponsored Programs