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Definitions and Scope

What is a Financial Conflict of Interest (FCOI)?

A Financial Conflict of Interest is a significant financial interest that could directly and significantly affect the design, conduct, or reporting or research and sponsored activities.

What is a Significant Financial Interest (SFI)?

A Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interests held by the Investigator or the Investigator’s family that reasonably appears to be related to the Investigator’s institutional responsibilities:

1. **Publicly traded entities (i.e. whose shares are purchased on an open stock market):** A SFI exists if remuneration from or an equity interest in a singular publicly traded entity exceeds $5,000 in the twelve (12) months preceding a disclosure, when aggregated as of the date of disclosure. Remuneration includes 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.

2. **Non-publicly traded entities (i.e. privately held companies):** A SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding a disclosure, when aggregated, exceeds $5,000; or when the Investigator holds any equity interest (e.g., stocks, stock options, or other ownership interests), whether or not it exceeds $5000.

3. **Intellectual property rights and interests (e.g., patents, copyrights):** A SFI exists upon receipt of any income related to such rights and interests.

4. **Sponsored Travel:** A SFI exists with the occurrence of any reimbursed travel, or sponsored travel (i.e., travel and incidentals paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. At a minimum, disclosure will include the purpose of the trip, name of the Sponsor or organizer, destination, and duration. The IO will determine if additional information is needed to determine whether the travel constitutes a SFI.

The term SFI does NOT include:

1. Salary, royalties, or other remuneration paid by the college to the Investigator if the Investigator is currently employed or otherwise appointed by Augsburg, including intellectual property rights assigned to Augsburg and agreements to share royalties related to such rights.

2. Income from certain 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.

3. Income from seminars, lectures, or teaching engagements, or income from service on advisory committees or review panels sponsored by a federal, state, or local government agency, an institution of higher education [as defined by the Higher Education Act 1965: 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.

4. Travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education [as defined by the Higher Education Act 1965: 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.
Who does the FCOI Policy apply to?

This policy applies to all Augsburg Investigators (faculty, staff, students, or other individuals) involved in the design, conduct, or reporting of Sponsored Activities.

Sponsored Activities include but are not limited to research, public service, instruction, and/or training activities funded by grants, contracts, cooperative agreements, and other sponsored agreements.

This policy may also apply to a Sub-recipient (an individual or external entity receiving financial assistance from Augsburg to conduct a substantive portion of a Sponsored Activity) where funding is received from a Public Health Service entity and the Sub-recipient does not have an applicable policy and procedure.

What is a Sponsored Activity?

Sponsored Activities include but are not limited to research, public service, instruction, and/or training activities funded by grants, contracts, cooperative agreements, and other sponsored agreements.

I've managed grants for several years. Why do I have to complete this requirement now?

In an effort to ensure research and other sponsored activities are conducted ethically and without bias, sponsors are now requiring grantee institutions to take a more active role in managing or eliminating any financial interests that could impact the design, conduct, or reporting of a funded project. This is especially true in the case of federal and state funding, where stewardship of public funds and maintaining trust is critical.

Additionally, in 2011 the Public Health Service (PHS) revised their regulations to promote objectivity and create greater transparency in publically funded research. These regulations became effective in August 2012 and require applicants for PHS funding to actively manage or eliminate any significant financial interests of investigators participating on the project. Additionally, the grantee must promptly disclose any identified financial conflict of interest to the sponsor, and where necessary, the public.

This policy has been designed to support the credibility of sponsored activities conducted at Augsburg, as well as meet federal and state regulations. It complies with the August 2012 Public Health Service (PHS) regulatory requirements as identified in 42 CFR 50 Subpart F and 45 CFR 94 and the National Science Foundation’s (NSF) policy on conflicts of interest found in Chapter IV.A of the Awards and Administration Guide.

I’m an Investigator on a funded project. What, specifically, must I do to be in compliance with the FCOI policy?

1. Read through the entire FCOI policy.
2. Complete web-based Conflict of Interest training (every 4 years).
3. Complete and sign the Financial Interest Disclosure Form (at least once, per year; updates as necessary).
Training Requirement

How often must I complete the training?
Once you have completed the initial conflict of interest training, a refresher course will be required every four (4) years. You should receive an automated alert from CITI several months before your training is due to expire; however, it is your responsibility to keep current with your training.

How long will the training take?
Approximately 40 minutes. The time it takes you may be more or less depending on your reading speed and familiarity with the topic.

How do I access the training?
Open your browser and go to https://www.citiprogram.org/ and log in if you are an existing user. Click on “Register” if you are a new user.

Detailed instructions are available using this link and also appear on page 11 of the full policy.

I see more than one training option available in my CITI training portal. Are these also required?
No. Only the “Conflict of Interest” course is required for this policy.

That said, keep in mind that your project or sponsor may require additional training. Be sure to check the program guidance or contact Erica Swift if you are not sure what is required of you. For example, NSF policy requires Responsible Conduct of Research training for all personnel (including students) participating on a funded project. Also, additional courses may be required by the IRB, IACUC, or another regulatory body.

Do I need to send my CITI training completion report to Sponsored Programs?
No. The Office of Sponsored Programs will receive an automatic notice that your training has been completed. You may wish to retain a copy of your completion report for your records, but it is not necessary as these reports can be accessed at any time through your CITI portal.

Disclosure Requirement

How often do I have to complete the financial disclosure form?
1. Annually (in September)
2. Within 30 days of acquiring or releasing a significant financial interest during the year.

The reporting period will run from September to August of each year. At a minimum, every investigator (faculty, staff, students, others) must complete the annual disclosure by September 30th of each year.
Additionally, the investigator must submit an updated form to reflect any changes (as applicable) within 30 days of acquiring or releasing a significant financial interest.

Current investigators (at the time this policy is implemented) will complete two annual disclosures in 2014. The initial disclosure will occur prior to the March 31, 2014 deadline. The subsequent disclosure will be completed in September 2014 and will continue annually in September thereafter.

Future investigators (those without current grant funding) will be asked to complete the annual disclosure prior to submitting a proposal for funding. These individuals will then follow the annual September deadline.

I don’t have anything to disclose. Do I still need to complete the form?
Yes. All Investigators (faculty, staff, students, or other individuals) involved in the design, conduct, or reporting of Sponsored Activities must complete the disclosure form, even if they do not have any significant financial interests to report.

Who do I send my completed disclosure form to?
Please send your completed disclosure forms to Erica Swift at swift@augsburg.edu.

Are my responses confidential?
All responses are kept strictly confidential and will be stored electronically on Augsburg’s password protected server. Paper copies will not be maintained.

I have financial interests to disclose. Will my financial interests prevent me from working on funded research or other funded projects?
Not necessarily. It is your responsibility to conduct your work in a manner that reduces potential conflicts of interest, but there may be circumstances where a conflict is unavoidable. If it is determined that a significant financial interest is considered to directly and significantly affect the design, conduct, or reporting or research and sponsored activities, the FCOI committee (composed of the Director of Sponsored Programs, Provost, and others as determined appropriate) will create a management plan for reducing or eliminating the conflict. This plan will be based on your current situation and the goals of the project. You will be expected to comply with the management plan for the duration of the project unless the interest is released prior to the end of the project period. See page seven (7) of the full policy for more information.