

UNION COLLEGE
Financial Disclosure Policy for All Investigators
Conducting Research Supported by Public Health Service Funding
(Financial Conflict of Interest)

Background

To address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among Government, research Institutions, and the private sector, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) published revised regulations on the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*, commonly known as the Financial Conflict of Interest (FCOI) regulations. These regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the **National Institutes of Health (NIH)**, for grants, cooperative agreements, and research contracts.

An Institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e., August 24, 2012, and immediately upon making the Institution's Financial Conflict of Interest policy publicly accessible as described in 42 CFR part 50.604(a).

Union College Policy Statement

Investigator (as defined below) activities shall be conducted in a manner that avoids inappropriate conflicts of interest. Conflicts of interest may occur when there is a divergence between a faculty member's private interests and professional services to the College. This policy is designed to assist investigators and the College in identifying potential and actual conflicts of interest and to support compliance with government regulations (see <http://grants.nih.gov/grants/policy/coi/index.htm>).

1) Disclosure of Significant Financial Interests

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 funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants (each, an "Investigator") are required to disclose to the College's Research Integrity Officer (the "RIO") all "Significant Financial Interests" of the Investigator and/or the Investigator's spouse, domestic partner, and/or dependent children. See paragraph 3 "Timing of Disclosures."

2) Significant Financial Interest

- a) Definition: A “Significant Financial Interest” (SFI) means one or more of the following interests, if it reasonably appears to be related to the Investigator’s institutional responsibilities, including all research, teaching, and/or service to the College:
- i) With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure *and* the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. Remuneration includes any salary and 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.
 - ii) With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, *or* when the Investigator (or spouse, domestic partner, and/or dependent children) owns *any* equity interest, regardless of dollar value.
 - iii) Intellectual property rights and interests (e.g., patents and copyrights) upon receipt of income related to such rights and interests. This does not include any income received from Union College for intellectual property rights assigned to Union College based on agreements to share in the royalties related to such rights in conformity with the College’s Intellectual Property policy.
 - iv) Any occurrence of reimbursed or sponsored travel (i.e., that which is 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 the Investigator’s institutional responsibilities must also be disclosed, with the exception of any travel 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 center affiliated with an institution of higher education. Travel that is reimbursed by Union College from a sponsored fund account whose sponsor is an entity that is not one of those exempt entities shall be treated as an SFI. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination, and the duration. Additional information, including the estimated cost of travel, may be requested by the RIO and must be furnished upon request.
- b) Exclusions: The term “Significant Financial Interest” does not include:
- i) Salary, royalties, or other remuneration from Union College;

- ii) Income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- iii) Income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education;
- iv) Income from service on advisory committees or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

3) Timing of Disclosures

- a) Investigators must provide all required financial disclosures *no later than* at the time a proposal seeking PHS funding is submitted.
- b) Investigators must update the disclosures:
 - i) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and
 - ii) Annually within the period of the award, beginning with the anniversary date of the original disclosure.

4) Process for the Review and Management of Financial Disclosures

- a) Determination: The RIO¹ shall review each disclosed SFI, determine whether such SFI relates to NIH-funded research, and if related, determine whether a Financial Conflict of Interest (as defined below) exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict of interest. The RIO may request that additional staff or faculty serve on an *ad hoc* review committee to assist in a timely review.
- b) Definition: A “Financial Conflict of Interest” exists when the institution, through its RIO, reasonably determines that an Investigator’s SFI is related to an NIH-funded research project and could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.
- c) Management of Financial Conflicts of Interest: : If the RIO determines that a SFI constitutes a Financial Conflict of Interest, the RIO will confer with the Union College

¹ For more information and the definition of RIO, please see the Scientific Misconduct Policy located in Section V-V of the Faculty Manual:

<https://www.union.edu/sites/default/files/academic-affairs/202001/fm-section-v-ethics-and-conduct.pdf>

Deciding Official (DO)² to review the research, the financial interests in question, and the areas of conflict, in order to make an informed plan for the management of the Financial Conflict of Interest (the “Management Plan”) to support the goals of the College as a recipient of PHS funds and the continued objective pursuit of research.

- i) The Investigator will be consulted as to the implementation of the Management Plan, and the Investigator must agree to the plan before PHS-funded research can proceed; if the RIO, DO and Investigator cannot agree to a management plan, the relevant regulatory body and funding agency will be notified.
- ii) Conditions or restrictions that might be imposed to manage an Investigator’s Financial Conflict of Interest include, but are not limited to:
 - Public disclosure of Financial Conflict of Interest (e.g., when presenting or publishing the research);
 - For research projects involving human subjects research, disclosure of the Financial Conflict of Interest directly to participants;
 - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;
 - Modification of the research plan;
 - Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
 - Reduction or elimination of the financial interest (e.g., sale of an equity interest);
 - Severance of relationships that create financial conflicts.

5) Reporting Financial Conflicts of Interest

- a) NIH (Sponsoring Agency): SFIs that are determined by the RIO to be Financial Conflicts of Interest will be reported to the sponsoring agency within 60 days of the original disclosure. Annual Financial Conflict of Interest reports shall be submitted through the NIH eRA Commons system in accordance with agency requirements.
- b) Public Request: Prior to the Institution’s expenditure of any funds under an NIH-funded research project, the Institution shall ensure public accessibility or written response within five business days of a request, of information concerning any SFI disclosed to the Institution that meets the following three criteria:

² For more information and the definition of Deciding Official, please see the Scientific Misconduct Policy located in Section V-V of the Faculty Manual:

<https://www.union.edu/sites/default/files/academic-affairs/202001/fm-section-v-ethics-and-conduct.pdf>

- i) The SFI was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- ii) The Institution determines that the SFI is related to the NIH-funded research;
- iii) The Institution determines that the SFI is a Financial Conflict of Interest

6) Subrecipients

- a) Institutional Responsibilities: The Institution is responsible for ensuring subrecipient's compliance with the regulation and reporting identified financial conflicts of interest for subrecipient Investigators to the NIH. Terms shall be written into all contractual agreements between Union College and the subrecipient establishing whether the Financial Conflict of Interest Policy of the awardee Institution or of the subrecipient will apply to subrecipient investigators. Furthermore, the terms of the agreement shall state the time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements. The Institution is responsible for monitoring subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and for reporting all identified financial conflicts of interest to the NIH.

7) Investigator Training

- a) The federal regulation requires that all Investigators complete training on the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* guidelines and the Institutional policy implemented as a response to this regulation. Training sessions will be organized and conducted by the Director of Sponsored Programs. Each Investigator must complete training prior to engaging in NIH-funded research and at least every four years, or immediately under the designated circumstances:
 - i) Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements;
 - ii) An Investigator is new to an Institution;
 - iii) An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan

8) Disclosure Statement

- a) The Union College *Financial Disclosure Form for All Investigators Conducting Research Supported by Public Health Service Funding* is available online at https://union-college.formstack.com/workflows/fcoi_phs. This disclosure form must be completed before submission of an NIH grant proposal. Once the form is submitted by the Investigator, the Director of College Grants & Sponsored Program will review the

form to determine if an SFI has been disclosed. If no SFIs have been disclosed, the Director of College Grants & Sponsored Programs will sign-off on the form, ending the disclosure process. If an SFI has been disclosed, the Director of College Grants & Sponsored Programs will forward the form to the RIO. The RIO will then review the form to determine whether the disclosed SFI relates to NIH-funded research, and if related, whether a Financial Conflict of Interest exists, along with what condition or restrictions are needed to manage, reduce, or eliminate such conflict of interest.

9) Additional Applicable Resources

- a)** To learn more about the federal regulation, Investigators are encouraged to review resources available online:
 - i)** NIH Financial Conflict of Interest Website:
<http://grants.nih.gov/grants/policy/coi/index.htm>
 - ii)** NIH Financial Conflict of Interest Tutorial:
https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html
 - iii)** Frequently Asked Questions:
<https://grants.nih.gov/faqs#/objectivity-in-research.htm>
 - iv)** Final Rule: Federal Register: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F):
<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>