PHS / NIH Financial Conflict of Interest Disclosure Form

Effective August 24, 2012, a significant change in the procedure for disclosing conflicts of interest was implemented to comply with new federal regulation regarding public health service funding. These requirements affect PHS-funded investigators who receive an award notice or no-cost extension with an issue date on or after August 24, 2012.

In accordance with the Management of Conflicts of Interest Related to Public Health Services Sponsored Awards for Research (42 C.F. Part 50, Subpart F and 45 C.F.R., Part 94), the Principal Investigator and all other Investigators must disclose their personal significant financial interests (and those of their spouse, registered domestic partner, and/or dependent children) related to their institutional responsibilities. This includes the Principal Investigator, Co-Investigators, Senior and Key Personnel, and any other individual who is responsible for the design, conduct, or reporting of research funded by PHS or an agency or organization that follows PHS disclosure requirements.

Who must submit this form?

If you are submitting a proposal to any of the below agencies, whether Skidmore College is the applicant or subcontractor, you and anyone defined as an **"Investigator"** on your proposed project must submit a Financial Conflict of Interest Disclosure Form:

1. Annually
2. Prior to the submission of an application for external research support to a PHS-funded agency
3. Within 30 days of a change in financial status (acquisition of new significant financial interest)

What must be disclosed?

All Significant Financial Interests related to an Investigator's Institutional Responsibilities.

Organizations That Require Compliance with PHS Regulations

U.S. Public Health Services Agencies include:

- 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 Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs (OGA)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Preparedness and Response (OASPR)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

PHS Required Financial Conflicts of Interest Training

Please note that effective August 24, 2012, each Investigator must complete Financial Conflicts of Interest Training:

- Prior to engaging in research related to any PHS-funded grant or contract;
- At least every four years; and
- Immediately under the following circumstances:
    - Institutional FCOI policies change in a manner that affects Investigator requirements;
    - An Investigator is new to Skidmore College; or
    - Skidmore College finds an Investigator noncompliant with Skidmore College's FCOI policy or management plan.

Project Information

Name: _____ Department: _____ Email: _____

Lead PI: _____ Lead PI Organization (if not Skidmore): _____

Role on Project: _____ Sponsor: _____ Project Dates: _____to _____

Project Title: _____

Are subrecipients involved in the project? ☐ No ☐ Yes

If yes, provide name(s) of subreceipient organization(s): _____

Type of Proposal/Disclosure

☐ New Proposal ☐ Update Disclosing New Significant Financial Interests

☐ New Investigator Added to Project ☐ Required Annual Update

1. Do you or any member of your immediate family (spouse, registered domestic partner and/or dependent children) have any Significant Financial Interests (SFI) in a **Publicly-Traded Entity** that might reasonably appear to be related to your Institutional Responsibilities? *An SFI for publicly-traded entities exists if the value of any equity interest as of the date of disclosure combined with any remuneration in the past 12 months exceeds $5,000.*

   ☐ Yes ☐ No

2. Do you or any member of your immediate family (spouse, registered domestic partner and/or dependent children) have any Significant Financial Interests (SFI) in a **Privately-Held Entity** that might reasonably appear to be related to your Institutional Responsibilities? *An SFI for privately-held entities exists if the value of any remuneration in the past 12 months exceeds $5,000, or when the Investigator or immediate family holds **any equity** interest.*

   ☐ Yes ☐ No

3. Have you or any member of your immediate family (spouse, registered domestic partner and/or dependent children) received **any income** related to **intellectual property** rights and interests that might reasonably appear to be related to your Institutional Responsibilities? (Do not include any intellectual property that has been assigned to Skidmore.)

   ☐ Yes ☐ No

4. In the past 12 months, have you undertaken any **travel** related to your Institutional Responsibilities that was either reimbursed or paid for by an individual or entity other than a Federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 100(s), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education?

   ☐ Yes ☐ No

Acknowledgement and Certification

I **acknowledge** that by signing my name below, it is my responsibility to disclose, *within 30 days*, any new significant financial interests obtained during the term of the above proposed project. I **certify,** to the best of my knowledge, that this disclosure of significant financial interests is complete and accurate.

Investigator Name: _____ Date: _____

Investigator Signature: _____

Definitions

Family means any member of the Investigator's immediate family, specifically, any dependent children, spouse or registered domestic partner.

Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

A. salary, royalties, or other remuneration from the Institution;

B. income from the authorship of academic or scholarly works;

C. income from 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 institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or

D. equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, ***Financial Interest*** also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

A. if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds $5,000; or

B. if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds $5,000; or

C. if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or

D. is income related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Institutional Responsibilities means the Investigator's responsibilities on behalf of Skidmore, which are defined by Skidmore as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards (e.g., IACUC, IBC, and IRB).

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS-sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health and the Centers for Disease Control.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).