



HOPE COLLEGE

Financial Conflict of Interest Policy (FCOI)

Version 1, August 21, 2012

SUMMARY

This document describes Hope's policy for identifying and managing Financial Conflict of Interests (FCOI). Federal regulations, according to citation 42 CFR 50 Subpart F, governing NIH¹ and NSF² grants require the College to establish, promote, administer, and enforce a publicly accessible FCOI policy. This policy is designed to disclose and ensure appropriate management of any FCOI as a result of an Investigator or senior personnel planning to participate in or is participating in a NIH or NSF funded project. Hope College must also provide all investigators and senior personnel who are applying for NIH or NSF funding to complete FCOI training prior to the proposal submission.

PROCESS TO INFORM INVESTIGATOR

The Investigators will be informed of the College's FCOI policy and procedures, including the required FCOI training, when the Investigator completes the College's Early Notification Form³. This online form is received by the Sponsored Research Office (SRO) and shared with the respective academic Dean and the Associate Dean for Research and Scholarship. The Investigator will indicate if there is a Significant Financial Investment (SFI) related to the proposed research. If so, the Investigator will be directed to the FCOI disclosure statement form.

TRAINING

Investigators and senior personnel must receive FCOI training at least every 4 years. Training must be immediate if an Investigator and/or senior personnel is: a) new to Hope College, b) Hope College revises its FCOI policy that affects requirements of Investigators or c) an Investigator is not in compliance with the policy or management plan.

- Current/Pending NIH/NSF funded Investigators: Investigators and senior personnel of currently funded or pending NIH and NSF grants prior to August 24, 2012 must complete training of the College's FCOI. This training will consist of a mandatory completion of the CITI FCOI mini-module (1 & 2) course administered by the Associate Dean for Research and Scholarship.
- New NIH/NSF grant applicants: New grant applicants (after August 24, 2012) who notify the (SRO) of their intent to apply for a NIH or NSF grant are required to complete the CITI FCOI mini-module training prior to the submission of the proposal.

¹NIH regulation <http://grants.nih.gov/grants/policy/coi/index.htm>

²NSF regulation http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/aag_index.jsp

³Sponsored Research Office Early Notification Form http://hope.edu/admin/osr/notification_form.html

- Investigators on or applying for non-NIH/NSF grants: For investigators sponsored by or seeking funding from non-NIH/NSF and/or other federal agencies, the above training activities are optional but strongly recommended.

DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST (SFI)

Hope College requires full-time faculty and senior personnel who propose to receive funds from NIH or NSF for research, materials development, training or equipment projects must disclose, prior to proposal submission, whether any conditions exist which might create an actual or apparent “Significant Financial Interest” (SFI). This disclosure is initiated when the Investigator answers YES to either of these two questions that appear on the College’s Early Notification Form.

1. Does the Investigator, senior personnel, his or her colleagues, family, or associates have a significant financial interest (over \$5000) or other conflict that would reasonably appear to be affected by the conduct or outcome of the grant-funded activities?
2. Will the significant financial interest potentially affect the integrity of the project, i.e. how the project is run or what kinds of results are reported?

The Investigator is then required to complete the FCOI Disclosure Form using the following SFI definitions and exceptions:

- SFI Definition – minimum threshold of \$5000 received within 12 months preceding disclosure
 1. *Equity Interest – Non-publicly traded entity* (e.g. stock, stock option, or other ownership interest).
 2. *Equity Interest – Publicly traded entity* (e.g. stock, stock option, or other ownership interest).
 3. *Intellectual property rights* (e.g. royalties, patents, copyrights) not from the awardee institution (Hope College)
 4. *Investment vehicles*, such as mutual funds and retirement accounts, controlled by the investigator. This does not include Hope College’s retirement packages.
 5. *Other* (provide and explanation that describes the SFI)
 6. *Payment for services* (e.g. consulting fees, honoraria, paid authorship)
 7. *Reimbursed or sponsored travel* – This includes responsibilities including instruction, research or service to Hope College, **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. The investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and

its duration. Additional information, including the estimated cost of travel, may be requested by Hope College administrators and must be furnished upon request.

8. *Salary not from the awardee institution*

- Exclusions – The term “Significant Financial Interest” does **not** include:
 1. Salary, royalties, or other remuneration from Hope College
 2. 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
 3. Income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutions affiliated with institutions of higher education
 4. 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.
 5. Unlicensed intellectual property that does not generate income.

A possible FCOI may not preclude acceptance of the grant or contract in question; but appropriate disclosures or other safeguards may need to be implemented and accepted by both the Investigator and the institution. Information received on possible financial interests in a proposed project will be kept strictly confidential, except where public disclosure is a safeguard the Investigator and College have agreed upon or such disclosure is required by law or court order.

In addition to completing the FCOI Disclosure Form, the Investigator must also indicate s/he has completed the form and has a SFI by checking a box and signing the External Support Routing Form. This External Support Routing Form is the official administrative approval for any external grant proposal.

TIMING OF SFI DISCLOSURES

Investigators and senior personnel must complete the FCOI Disclosure Statement Form prior to the submission of the proposal.

If a FCOI is disclosed, the Investigator or senior personnel must update the financial disclosures:

1. Within 30 days of discovering or acquiring any new SFI; and
2. Annually within the period of the award, beginning with the anniversary date of the original disclosure

DISCLOSURE STATEMENT FORM

The FCOI disclosure statement form⁴ is available on the Sponsored Research Office website. The form must be completed by all senior personnel who are submitting proposals to the NIH or NSF. The NIH required assurance certification form⁵ cannot be

signed until FCOI forms for all Investigators and senior personnel are submitted to her/his designated academic Dean. By signing this form the applicant certifies that he/she has read this section of the Faculty Handbook and that he/she either:

- a) does not have potential FCOI or
- b) does have potential conflicts

In either case, the applicant also declares that he/she will notify the designated academic Dean of any change or discovery requiring modification of the above statement.

INTERNAL REVIEW OF SFI DISCLOSURES

Upon receiving the confidential disclosure from the Investigator or senior personnel, the designated academic Dean will determine if the SFI directly or significantly affects the design, conduct, or reporting of the research or educational activity.

If it does, the Dean, in consultation with the Provost, will assemble an administrative panel to review the disclosure and the potential of a FCOI. The panel will be composed of representatives from the Provost's Office, the Dean's Office of the appropriate academic division, Associate Dean for Research and Scholarship, the Sponsored Research Office, and the College's Legal Counsel. Appropriate senior faculty members may also be impaneled if their expertise is required. If a potential conflict is present, management steps will be proposed, discussed with the Investigator, and then stipulated as conditions for expenditure of the award.

The above policy refers only to externally sponsored research, materials development, training, and other types of program delivery in which funds are awarded to or handled by the College. External funding awarded directly to an Investigator rather than through the College must be reported to the Provost as outside employment.

The College reserves the right to require faculty or other employees to follow the procedure described above if the outside employment project substantively involves use of other College personnel or College resources other than use of the Investigator's office space, office computer, and comparable standard resources provided to individual faculty members.

MANAGEMENT PLAN (MP) of FCOI

After review determines that a conflict exists, the College, following discussion with the Investigator, may require that any of a wide range of steps be taken. These may range from disclosure to the funding agency, to disclosure in public announcements, to special monitoring arrangements, to divestment of the conflicting interest.

⁴ Disclosure Statement Form <http://hope.edu/admin/osr/forms.html>

⁵ NIH Assurance Certification Form http://hope.edu/admin/osr/pdf/Hope_College_NIH_PI_assurance_certification_form.pdf

The management plan may include conditions or restrictions to manage, reduce, or eliminate FCOI, which may include (but may not be limited to):

- a) Monitoring of research by independent reviewer
- b) Modification of the research plan
- c) Disqualification from participation in the portion of the funded research that would be affected by SFI
- d) Divestiture of SFI
- e) Severance of relationships that create conflicts
- f) Public disclosure of FCOI

The Investigator and/or senior personnel will be consulted as to the implementation of the MP who must agree to the plan before the research can proceed. If the FCOI committee and the Investigator cannot agree upon a MP, the relevant regulatory bodies and funding agencies will be notified.

ENFORCEMENT

The College shall “establish adequate enforcement mechanisms and provide for employee sanctions”, but also to provide for other administrative actions to ensure Investigator compliance as appropriate”. Disciplinary proceedings initiated in connection with this policy shall be conducted in accordance with the Hope College Faculty Handbook or the Student Code of Conduct. All relevant regulatory bodies and funding agencies will be promptly informed of disciplinary sanctions.

RECORDS

The College shall maintain records of all financial disclosures and all actions taken to resolve FCOI for at least 3 years from the date the final expenditures report is submitted to the federal agency, or until the resolution of any federal action involving those records, whichever is longer.

SUB RECIPIENTS

The College is responsible for ensuring all sub recipients’ compliance with the applicable federal regulations regarding FCOI. When an Investigator notifies the College of her/his intent to apply for a NIH or NSF grant using the Early Notification Form, s/he will identify on this form if a sub recipient is affiliated with the project. It is the responsibility of the Investigator to ensure the sub recipient provides any necessary FCOI documentation prior to the proposal submission.

To this end, the College shall enter a written agreement with each sub recipient that shall specify whether this policy, or the applicable policy of the sub recipient’s institution, will apply to sub recipient Investigators. Said agreement will specify the timing for reporting of FCOIs by sub recipients to Hope College to enable the timely review and reporting of such FCOIs in compliance with funding agency requirements. The College will report to the federal agencies within 60 days of any subsequently identified FCOI.