

# Financial Conflict of Interest for Grant-Funded Research or Other Academic Projects

## 1) Policy Statement:

In accordance with federal regulations and in keeping with St. Olaf's commitment to the highest standards of integrity and ethics in research, St. Olaf College ("College") has a responsibility to assess and manage any actual, potential or perceived conflicts of interest that may be presented by research or academic project grant applications and the financial interests of Investigators. Investigators who propose to receive funds from an external source for research or academic projects must disclose any actual, potential or perceived significant financial interest that would or could be affected by external funds. A possible conflict of interest does not preclude acceptance of external funding, but appropriate disclosures or other safeguards may need to be implemented and accepted by the Investigator(s), the College and, when applicable, the external funder.

## 2) Definitions for this policy:

- a) **College Leadership** for the purposes of the policy means one or more of the persons in the following positions, President, Provost, vice President for Human Resources, Vice President and Chief Financial Officer, Vice President and General Counsel and/or Controller.
- b) **Financial conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research or academic project.
- c) **Financial Interest** means anything of value, whether or not the value is readily ascertainable, including but not limited to cash compensation and stock or options in a company, whether publicly traded or privately held.
- d) **Institution of Higher Education** means an educational institution in the United States that is a public or other nonprofit institution and meets the other requirements set forth in 20 U.S.C, 1001(a). It does not include any college, university or institute outside the United States.
- e) **Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of the College, including all activities that derive or descend from the Investigator's standing or expertise and are tied to those responsibilities and activities the Investigator was hired to perform and for which the Investigator is paid by the College. Some examples are, Research, Research consultation, teaching, professional

practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

- f) **Investigator** means the project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or other educational activities funded or proposed for funding by an external public or private entity.

This includes but is not limited to the National Science Foundation (“NSF”), the National Institutes of Health (NIH), the Public Health Service (PHS) of the U.S. Dept. of Health and Human Services (HHS), the Department of Education, etc. This may include, for example, collaborators or consultants.

- g) **Management Plan** means a written agreement between the College and an Investigator to manage an FCOI.
- h) **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to an area of study, (e.g., 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). This term includes, but is not limited to, any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, NSF, etc. such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. This term also includes educational activities funded by the NSF, Dept. of Education, etc.
- i) **Senior/Key Personnel** means the PD/PI and any other person identified as senior/key personnel by the College in the grant application, progress report, or any other report submitted to the federal sponsor by the College under this policy.
- j) **Significant Financial Interest (SFI)** means a financial interest, consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
- (1) With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes 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;
  - (2) With regard to any non-publicly traded entity, an SFI exists if the value of any

remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

- (3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- ii) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator, or the Investigator's spouse and dependent children, and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the externally funded research.
  - iii) The term significant financial interest does not include the following types of financial interests:
    - salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
    - income from 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;
    - income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an 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<sup>1</sup>;
    - income from service on advisory committees or review panels for a Federal, state, or local government agency, an 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.

<sup>1</sup> For the avoidance of doubt, any financial interests received from a foreign government office, unit or agency (local, provincial/state or national), a foreign Institution of Higher Education, a foreign academic teaching hospital, a foreign medical center, or a foreign research institute must be disclosed. This also applies to income from service on a foreign advisory committee as described in the next bullet regarding service on an advisory committee or review panel.

- k) **Small Business Innovation Research (“SBIR”) Program** means the extramural Research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program also includes the Small Business Technology Transfer (“STTR”) Program, which was established by Public Law 102-564.

### 3) **Disclosure:**

The Investigator must disclose and/or update, as applicable, all SFIs, and those of the Investigator’s spouse and dependent children to the Associate Provost on the following occasions:

- a) Prior to grant submission: Prior to submitting a grant, the Investigator must complete a Proposal Clearance Form which includes a Conflict of Interest Certification.
- b) Annually during the term of the grant: The Finance Office notifies and requires all Investigators with open awards to renew their Conflict of Interest Certification on-line annually. The Finance Office is responsible for notifying the Associate Provost of any FCOI related to externally funded research.
- c) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, inheritance, etc.) a new SFI: If a new SFI is discovered or acquired the Investigator must submit a Declaration of Conflict of Interest Form (available on the College’s Business Office website) to the Associate Provost. Additional disclosures may be required based on the specific grant or other funding requirements.
- d) Upon employment at the College if the Investigator will be involved in externally funded research upon joining the College.
- e) Prior to expenditure or use of any externally funded Research. The Investigator must submit a Declaration of Conflict of Interest Form if an SFI has arisen since or was declared on the Proposal Clearance Form prior to the request for funding (see “a” above). Also, if the award was funded more than 1 year after the proposal was submitted to the funder.

It is the responsibility of the PI/PD to ensure that each Investigator working under their direction on a Research project or receiving support from their grant or contract receives a copy of this Policy and submits the proper disclosure form(s) required by this Policy.

Reimbursed or sponsored travel from a single entity (or related entities) that does not exceed \$5,000 in a year (including any reimbursed or sponsored travel for an Investigator's Immediate Family members) is not required to be disclosed.

The details of this disclosure of reimbursed or sponsored travel must include, at a minimum:

- Dollar amount or value (which may be estimated for sponsored travel whose value reasonably appears to exceed \$5000)
- Purpose of the trip
- Identity of the sponsor/organizer
- Destination
- Duration of the trip
- The name(s) of the Investigator's spouse or dependent children, if such individuals were reimbursed or sponsored travel.

#### **4) Review and Monitoring Requirements:**

The Associate Provost will review all SFI disclosures for external funded Research to determine whether an actual, potential or perceived conflict of interest exists. The review of SFIs shall occur prior to the College's expenditure or any funds (or prior to a funding application submission, if required) and within 60 days upon any disclosure by an Investigator.

If an FCOI exists the Associate Provost, in consultation with College Leadership, shall prepare a Management Plan to manage, reduce or eliminate any actual, potential or perceived FCOI(s). A Management Plan may include conditions or restrictions such as, but not limited to:

- a) public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research)
- b) For research projects involving human subjects research, disclosure of financial conflict of interest directly to participants;
- c) 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;
- d) modification of the research plan;
- e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of research;
- f) Divestiture or elimination of financial interests; or severance of relationships that create conflicts.

When the Associate Provost, in consultation with College Leadership, determines that the FCOI cannot be managed, the conflict must be eliminated or the Research prohibited. Factors to consider when making that determination include such considerations as:

- the involvement of human or animal subjects in the Research,

- the level of risk involved,
- the nature and significance of the conflict,
- the potential for having a serious adverse impact on the scientific field or on the reputation of the College, and
- the level of difficulty involved in managing the conflict relative to the benefit of doing the Research.

An approved plan for management or elimination of the FCOI must be in place before Research begins. Grant applications may be submitted while the College is considering an SFI, provided that the College will not draw down or utilize the funds unless the FCOI can be managed or eliminated.

Nothing in this Policy shall be construed to preclude the College from imposing, in its sole discretion, a Management Plan with respect to an SFI determined not to rise to the level of an FCOI or a financial interest that does not rise to the level of an SFI but is determined to conflict with an Investigator's Institutional Responsibilities.

When the College implements a Management Plan, it will monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the funded Research project or the elimination of the conflict whichever comes first.

## **5) Reporting:**

### **A. PHS-Specific Reporting Requirements**

This section applies only to awards funded by PHS Awarding Components, including NIH. It does not require reporting of FCOIs for projects not funded by PHS Awarding Components. However, the College may in its discretion require external reporting of identified FCOIs in other circumstances (*e.g.*, as required by another entity funded award).

Prior to drawing down or utilizing any funds under a PHS award, the College must report to the PHS awarding component the existence of an FCOI (including an FCOI of any subrecipient) in an FCOI Report. In these cases, the College will ensure the interest has been managed, reduced, or eliminated in accordance with the regulation.

For Investigators who are new to a project, or for newly identified FCOIs for existing Investigators, an FCOI Report shall be submitted within 60 days of identification of the FCOI.

For any FCOIs previously reported by the College with regard to an ongoing PHS-funded Research project, the College will provide to the PHS Awarding Component an annual FCOI Report that addresses the status of the FCOIs and any changes to the Management Plan for the duration of the PHS-funded Research project. The annual FCOI Report will specify whether the financial conflict is still being managed or explain why the FCOIs no longer exists. The College will provide annual FCOI Reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

## **B. NSF Reporting Requirements**

If the Research is sponsored by the NSF, the College's registered NSF contact will keep the NSF's Office of the General Counsel appropriately informed if the College finds that it is unable to manage satisfactorily an FCOI.

## **C. The FCOI Report**

Any FCOI Report required by the regulation shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the College's Management Plan. Elements of the FCOI Report shall include, but are not necessarily limited to the following:

1. Project/Contract number;
2. Project Title
3. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOIs;
5. Name of the entity with which the Investigator has an FCOI;
6. Nature of the financial interest (*e.g.*, equity, consulting fee, travel reimbursement, honorarium);
7. Value of the financial interest (dollar ranges are: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
8. A description of how the financial interest relates to the PHS-funded Research and the basis for the College's determination that the financial interest conflicts with such Research; and
9. A description of the key elements of the College's Management Plan, including:
  - Role and principal duties of the conflicted Investigator in the Research project;
  - Conditions of the Management Plan;
  - How the Management Plan is designed to safeguard objectivity in the Research project;
  - Confirmation of the Investigator's agreement to the Management Plan;
  - How the Management Plan will be monitored to ensure Investigator compliance; and
  - Other information as needed.

## **6) Untimely Disclosures and Failures to Review SFIs**

### **A. Review**

When the College identifies an SFI that was not disclosed timely by an Investigator or was not previously reviewed by the College during an ongoing sponsored Research

project (*e.g.*, was not timely reviewed or reported by a subrecipient), the Associate Provost will:

- review the SFI,
- determine whether it is related to federally-funded Research,
- determine whether an FCOI exists, and, if so:
- Implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to manage such FCOIs going forward.

The Associate Provost shall review the new SFI promptly, so that the College can meet its obligation to disclose any subsequently identified FCOIs to a PHS Awarding Component within 60 days.

All PHS-funded Research is subject to the requirements under Section 10, when there has been an unidentified and/or unmanaged FCOI in PHS-funded research.

## **B. Management**

Depending on the nature of the FCOI, the Associate Provost and/or College Leadership may determine that additional interim measures are necessary with regard to the Investigator's participation in the Research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of the retrospective review. In those cases, the Associate Provost in consultation with College Leadership may impose interim management measures.

When it is determined that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not timely managed or reported by the College as required by applicable federal regulations, the College shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations or papers.

## **7) Retrospective Review of Unidentified or Unmanaged FCOIs in PHS-Funded Research**

### **A. Review**

Whenever (i) an FCOI is not identified or managed in a timely manner; (ii) the College fails to review or manage FCOIs; or (iii) the Investigator fails to comply with an FCOI Management Plan, the College will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the sponsored Research project to determine whether any Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research.

The College is required to document the retrospective review and such documentation shall include, but not necessarily be limited to, all of the following key elements:



- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

#### **B. Updates to FCOI Report and Mitigation Report**

Based on the results of the retrospective review, the College will update the previously submitted FCOI Report, specifying the actions that will be taken to manage the FCOI going forward.

Further, if bias was found, the College promptly will notify the PHS or other federal awarding component, if any, and submit a mitigation report, including at a minimum the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the College's plan of action or actions taken to eliminate or mitigate the effect of the bias (*e.g.*, impact on the Research; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research project is salvageable). If the PHS refers the matter back to the College for further action with directions on how to maintain appropriate objectivity in the PHS-funded Research project, the College will cooperate with such directions.

### **8) Record Retention**

The Associate Provost and Finance Office will maintain records relating to all Investigator disclosures of financial interests and St Olaf's review of, and response to, such disclosures (whether or not a disclosure resulted in St. Olaf's determination of an FCOI) and all actions under this policy or retrospective review, including any Management Plans, for the longest of at least six years from:

- The date the final expenditures report is submitted to the PHS or another federal agency;
- When applicable, the starting dates specified in 45 CFR § 75.361 or § 94.4;
- The date of final payment;
- When applicable, for the time periods specified in 48 CFR Part 4, Subpart 4.7; or
- Until resolution of any federal agency action involving those records.

### **9) PHS Award Subrecipient Requirements:**

If the College carries out PHS-funded Research through a sub-recipient (*e.g.*, subcontractors or consortium members), the College as the awardee institution will incorporate as part of a written agreement with the sub-recipient terms that establish

whether this policy or the sub-recipient's own FCOI policy will apply to the sub-recipient's Investigators.

If the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the sub-recipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. If the sub-recipient's Investigators must comply with the sub-recipient's FCOI policy, the agreement referenced above shall specify time period(s) for the sub-recipient to report all identified FCOIs to St. Olaf's Government, Foundation and Corporate Relations (GFCR) office with the same level of detail as required in Section 5 above. Such time period(s) shall be sufficient to enable the College to provide timely FCOI Reports, as necessary, to the PHS as required by 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. After it receives a report of any FCOI identified by a sub-recipient, St. Olaf may, at its sole discretion, impose any additional conflict management measures that it deems necessary, and such measures will be communicated to the sub-recipient through St. Olaf's GFCR office.

If the sub-recipient cannot, or does not, provide such certification, the agreement shall state that sub-recipient Investigators are subject to St. Olaf's policy for disclosing SFIs that are directly related to the sub-recipient's work for St. Olaf. The agreement shall specify the manner and time in which the sub-recipient's investigators are to disclose SFIs to the St. Olaf's GFCR office. Such time period(s) shall be sufficient to enable the Associate Provost to comply timely with its review, management, and reporting obligations under 42 CFR Part 50 Subpart F or 45 CFR Part 94, as applicable. When the sub-recipient is required by the agreement to comply with St. Olaf's policy, the reporting requirement will be carried out by and through St. Olaf's GFCR office.

St. Olaf's GFCR office is responsible for notifying the Associate Provost of all FCOIs reported.

## **10) Human Subjects Research:**

### **A. Presumption Against Interested Human Subjects Research:**

When Research could involve risk to human subjects, the protection of those subjects must be of paramount concern. The College adheres to a rebuttable presumption that a financially interested Investigator will not be permitted to conduct any related Research that involves interventions with human subjects. Management of an identified FCOI must include development and implementation of a Management Plan that specifies the actions that have been or will be taken to manage such FCOI. For a similar presumption that applies to human subject research in which the College as an Institution has an interest.

### **B. IRB/IACUC Review:**

The College's IRB has responsibility for approving human subjects Research and the College's Institutional Animal Care and Use Committee has responsibility for approving animal subjects Research. Nothing in this Policy shall be construed to affect their authority to determine if Research under their jurisdictions is allowed to proceed under the terms of the Management Plan developed by the Associate Provost.

With respect to human subjects and animal Research, the Associate Provost will provide to the IRB or IACUC, as applicable, a notice of any SFIs and whether they were determined to constitute FCOIs for Investigators and a copy of any Management Plan imposed.

Because Investigators must submit to the IRB a conflict of interest disclosure for each protocol involving human subject Research, the IRB will facilitate review by forwarding any possible conflict of interest to the Associate Provost for review and management under this Policy.

The College may prohibit Research that involves an FCOI even if the IRB approves the Research.

Members of the IRB and IACUC must maintain all Investigator financial disclosure information in strict confidence, subject only to disclosure to the Associate Provost and College Leadership who have reason to know and inquire of such matters, and as otherwise required by law.

## **11) Training and Dissemination:**

Investigators will receive training on this policy when i) awarded a new grant or ii) when new to the College and will be involved with externally funded research. If the policy is substantively amended in a manner that affects the requirements of Investigators the entire faculty will receive notice of the update via email.

In addition, Investigators engaging in research funded by PHS/NIH must complete training on this policy prior to spending on their award, at least every four years thereafter, and in the event that this policy is substantively amended in a manner that affects the requirements of Investigators or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities. This policy will be publicly available on the St. Olaf website.

## **12) Enforcement and Retaliation:**

The Investigator's supervisor and Associate Provost, to the extent feasible, will monitor Investigators' compliance with this Policy and applicable Management Plans and will refer any suspected violations to the Provost.

If the Associate Provost finds that an Investigator has violated this Policy or the terms of an applicable Management Plan, the Associate Provost, in consultation with College Leadership, will impose appropriate disciplinary action. Disciplinary action may include actions such as the removal of an individual as PI of a Research study or termination of employment.

Allowing an FCOI to influence one's judgment in the context of Research may also constitute scientific misconduct, which may result in disciplinary action under the College's Research Misconduct Policy (see the College's Faculty Handbook,) and can also violate College policies relating to human subjects and animal research, for which the Investigator can be held accountable under the applicable policy.

Any act of retaliation or reprisal against an individual for reporting in good faith a

potential conflict of interest of another individual or a violation of this Policy by another individual shall be a violation of this Policy. Any use of this Policy to report in bad faith an alleged potential conflict of interest by another individual shall be a violation of this Policy. Such violations will be dealt with through regular administrative processes for violations of College policies.

### **13) Public Accessibility Requirements:**

Prior to the College's expenditure of any funds under a PHS-funded Research project, the College will ensure public accessibility, via a written response to any requester within five business days of a request, of information concerning any SFI disclosed to the College that meets the following three criteria:

- The SFI was disclosed and is still held by Senior/Key Personnel;
- The College determines that the SFI is related to the PHS-funded Research; and
- The College determines that the SFI is an FCOI.

The information that the College makes available via a written response to any requester within five business days of a request, will include, at a minimum, the following:

- A. Investigator's name;
- B. Investigator's title and role with respect to the Research project;
- C. Name of the entity in which the SFI is held;
- D. Nature of the SFI; and the approximate dollar value of the SFI
  - Dollar ranges are: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The College will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the College's identification of a new FCOIs, which must be requested subsequently by the requestor.

Information concerning the SFIs of an individual subject to this Policy shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

Written request should be mailed to:

Associate Vice Provost  
St. Olaf College  
1520 St. Olaf Ave.  
Northfield, MN 55057