

William College

Financial Conflict of Interest for Grant-Funded Research at Williams College

Effective Date: June 17, 2022*

Approval Date: June 17, 2022

Approval Office: Dean of Faculty Office

Responsible Office: Grants Office/Dean of Faculty Office

Responsible College Official: Director, Grants Office

Purpose: Williams College recognizes the importance of research integrity and in an effort to protect research and educational activities, has adopted this policy to appropriately manage conflicts or potential financial conflicts of interest. This policy also ensures compliance with the financial conflict of interest (FCOI), policies of the National Institutes of Health (NIH), the National Science Foundation (NSF) as well as other federal agencies who have or will adopt standards similar to the NIH. The policy was developed in response to the 2011 federal regulations that govern institutional and research responsibilities in identifying and monitoring conflicts of interest. By assuming this responsibility for ourselves, the college may avoid outside monitoring and regulation by the federal government.

Scope: This policy applies to all Williams College faculty and staff applying for external grants. The policy also applies to project directors or project investigators carrying out externally funded research/projects as subrecipients, contractors, or consultants of the college.

Definitions:

Significant Financial Interest (SFI) – consists of financial interests (all financial interests that have monetary value, whether or not the value is readily ascertainable), that reasonably appear to be related to the investigator's (and those of the investigator's spouse or partner and dependent children) institutional responsibilities, including all research, teaching, and/or service to the college:

- A. With regard to any *publicly traded entity*, a 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 disclosure, exceeds \$5,000. "Remuneration" includes: salary, any payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), reimbursed or sponsored travel, and any equity interests, including stock, stock options, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.
- B. With regard to any *non-publicly traded entity*, a 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 as of the date of disclosure, exceeds \$5,000, or when the investigator (or spouse, partner, or dependent children) holds *any* equity interest regardless of dollar value.

C. With regard to intellectual property (IP) rights and interests (e.g., patents and copyrights), upon receipt of income related to such right and interests must be disclosed. Royalties are potentially subject to disclosure, as are other interests related to intellectual property. Royalties and agreements to share in royalties related to IP rights paid to an investigator (or spouse, partner, or dependent children) are covered by the regulation and are subject to the \$5,000 threshold. If the royalties paid to the investigator (or spouse, partner, or dependent children) satisfy the definition of 'SFI,' then they must be disclosed. However, if the royalties or agreement to share in royalties relate to IP owned by the employing or appointing applicant or awardee institution and are licensed or potentially licensed through the applicant or awardee institution (i.e., they are not personally owned by the investigator), they are considered remuneration from the institution and would not be considered an SFI of the investigator. Royalties received by the investigator from the college would be excluded from the definition of SFI if the investigator is currently employed or otherwise appointed by the college.

- Unlicensed IP that does not generate income is also excluded from the definition of SFI. Nonetheless, such interests have the potential to become significant and generate income, at which point they would become subject to regulation and disclosure would be required.

D. With regard to sponsored travel, investigators must also disclose the occurrence of any reimbursed or sponsored travel, related to their institutional responsibilities, subject to the \$5,000 threshold. However, 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 college's FCOI policy specifies the details of this disclosure, which will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the college's FCOI policy, the director of the grants office will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether travel constitutes an FCOI with federally funded research.

Exclusions: SFI does NOT include the following types of financial interests: salary, royalties, or other remuneration paid by the college to the investigator if the investigator is currently employed or otherwise appointed by the college, including intellectual property rights assigned to the college and agreements to share in royalties related to such rights; 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; or income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Foreign Interests: References to institution of higher education refer to U.S. institutions, and references to federal, state, and local governments refer to agencies within the U.S. Therefore, investigators, including subrecipient investigators, must disclose all financial interests received from a foreign institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).

Procedures:

Disclosure of Significant Financial Interests: all personnel responsible for the design, conduct, or reporting of research under the terms of a grant or contract (Project Investigator/PI and/or Co-PI, and all senior personnel) are required to disclose to the grants office using the Financial Conflict of Interest Disclosure Form, all Significant Financial Interests of the investigator and/or the investigator's spouse, partner, and dependent children. If uncertain as to the appropriateness of listing a particular relationship, the director of the grants office, as institutional grants administrator, should be consulted. This policy also applies to subrecipient investigators. Conflicts of interest are frequently matters of judgement and degree; the college expects project investigators to be aware of possible effects of outside activities on the integrity of their decisions and on their ability to fulfill their obligations to the college and/or the funding agencies. As potential or actual conflicts of interest arise, the director of the grants office will determine which conditions or restrictions might be applied to manage, reduce, or eliminate actual or potential conflicts of interest. Records of financial disclosures will be maintained for at least three years from the date of submission of project final reports. The college will make conflict information available, upon request, to federal agencies.

Timing of Required Disclosures:

- A.** Investigators must provide all required financial disclosures to the grants office at the time of proposal submission
- B.** In addition, investigators must update those financial disclosures:
 - 1. Within 30 days of discovering or acquiring (e.g., through purchase, gift, marriage, or inheritance) any new Significant Financial Interest; and
 - 2. Annually within the period of the award, beginning with the anniversary date of the original disclosure

Review of Financial Disclosures: The following process shall apply to financial disclosures submitted by Investigators:

Determination of Financial Conflicts of Interest: The grants office shall review each disclosed SFI to determine whether such SFI relates to funded research, and, if so related, determine whether a Financial Conflict of Interest potentially exists. If the grants office finds a possible

conflict of interest at the time of proposal submission, a recommendation for elimination or mitigation of the conflict along with the disclosure form will be forwarded to the dean of faculty and associate provost for further review.

- ***Financial Conflict of Interest:*** A Financial Conflict of Interest exists when the dean of faculty and associate provost reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of funded research or educational activities.

Management Plan: The associate provost and the dean of faculty will review all disclosure statements which indicate a possible conflict of interest and make the final determination as to which financial conflicts can be managed in a way that protects the integrity of the funded research and the college and which cannot. The associate provost will ultimately be responsible for approving all plans for the elimination or mitigation of a possible conflict, including specification of the conditions under which an award can be accepted.

The director of the grants office will work with the Investigator to submit to the associate provost and dean of faculty a plan for elimination or mitigation of the apparent conflict of interest within 30 days. The management plan may incorporate conditions or restrictions to manage, reduce, or eliminate the Financial Conflict of Interest and may include but is not limited to the following:

- A. Monitoring of research by independent reviewers;
- B. Modification of the research plan;
- C. Disqualification from participation in the portion of federally funded research likely to be affected by the conflict;
- D. Divestiture of Significant Financial Interests
- E. Severance of relationships that create conflicts; and/or
- F. Public disclosure of Financial Conflicts of Interest.

The investigator must agree to the plan before research can begin. If agreement regarding a management plan cannot be reached, the relevant regulatory bodies and funding agencies will be notified.

Non-Compliance: if an investigator violates this policy, the director of the grants office will recommend appropriate action to the dean of faculty and associate provost. The dean of faculty and associate provost will make the final decision regarding any sanctions to be administered.

The college will also follow all applicable regulations regarding the notification of the sponsoring agency in the event an investigator fails to comply with the policy. The sponsor may take its own action(s) as it deems appropriate, including the suspension of funding for the investigator until a resolution is reached.

If the conflict arises in connection with clinical research undertaken to evaluate the safety or effectiveness of a drug, medical device, or treatment plan, the college will require disclosure of the conflict of interest in each public presentation of research results.

Reporting of Financial Conflicts of Interest:

- Sponsoring Agency – Significant Financial Interests determined to be Financial Conflicts of Interest will be reported to the sponsoring agency, in accordance with its requirements, and within 60 days of the original disclosure.
- Public Requests – As required by sponsoring agency regulation, information regarding the nature of conflicts of interest, indicating the investigator name and research project, will be made available to the public in response to inquiries within five business days of receipt of such requests.

Enforcement: the college will monitor and enforce this policy and provide sanctions as appropriate. Disciplinary action initiated in conjunction with this policy will be conducted in accordance with the College Faculty Handbook. All relevant funding agencies and regulatory bodies will be promptly notified of any disciplinary actions.

Records: the college will retain records of all financial disclosures as well as any actions taken to resolve any conflicts for at least three years beyond termination or completion of the grant award to which they relate, or until the resolution of any federal action involving the records, whichever term is longer.

Training: Investigators and all senior personnel on NIH/PHS-funded projects (and/or any other Public Health Service (PHS)-affiliated agencies) must complete the NIH's FCOI training program on the [FCOI website](#), which is designed to train investigators about FCOI regulations.

- New or previously unfunded investigators who notify the grants office of their plans to submit a research proposal to NIH or another PHS-affiliated agency after June 17, 2022, will be required to complete the NIH FCOI training (and complete the disclosure form described above) prior to submission of their proposals.
- For investigators on non-NIH/PHS projects seeking funding from NSF and/or other federal agencies, as well as investigators initiating research sponsored by a private for-profit entity, the above training activities are optional but strongly recommended. The disclosure form **is** required and must be completed at the time of proposal submission.
- Repeat training for active NIH/PHS-funded investigators, consisting of the NIH FCOI training, will be repeated every four years, and any time the college updates its financial conflict of interest policy or procedures.

Retrospective Review and Mitigation: Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- A. Failure by the investigator to disclose a SFI that is determined by the college to constitute a Financial Conflict of Interest;
- B. Failure by the college to review or manage such a Financial Conflict of Interest; or
- C. Failure by the investigator to comply with a Financial Conflict of Interest management plan;

The college shall, within 120 days of the college's determination of noncompliance, complete a "retrospective review" of the investigator's activities and the federally funded research project to determine whether any federally funded 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 shall document the retrospective review and will include the following elements:

- A. Project number
- B. Project title
- C. PI or contact PI if multiple PI model is used
- D. Name of the investigator with the FCOI
- E. Name of the entity with which the investigator has a financial conflict of interest
- F. Reason for the retrospective review
- G. Detailed methodology used for the retrospective review
- H. Findings of the review
- I. Conclusions of the review

If bias is found, the college will notify the appropriate federal funding agency and promptly submit a mitigation report. If the FCOI was previously reported to the federal funder, the mitigation report will be submitted as a 'revised FCOI report.' The mitigation report will include the key elements documented in the retrospective review above and a description of the impact of the bias on the research project as well as the college's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project; 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). Thereafter, the college will submit FCOI reports annually.

Disclosure Statement: The college's [Disclosure Statement](#) is available by contacting the grants office and on the Grants Office Policy webpage. The disclosure form must be completed by all investigators and senior personnel who are submitting proposals seeking external funding. The certification page of a proposal cannot be signed until forms for all investigators have been submitted to the grants office for review. By signing the form, the grant applicant certifies that they have read the Financial Conflict of Interest Policy and that they either do or do not have

potential Financial Conflicts of Interest. The grant applicant also declares that they will notify the grants office of any change or any discovery requiring modification of the above disclosure statement.

Subrecipients: The college is responsible for ensuring compliance from all subrecipients with the applicable federal and private regulations regarding Financial Conflicts of Interest. The college will include in each subrecipient agreement a written declaration specifying whether this policy, or the applicable policy of the subrecipient organization, will apply to the subrecipient investigator. The subrecipient agreement will specify the timing for reporting of FCOIs by subrecipients to Williams College to enable a timely review and reporting of any FCOIs in compliance with funding agency requirements.

*Replaces existing/outdated policy on Williams College website