

Colby College
Financial Conflict of Interest (FCOI) Policy
for the National Institutes of Health Grants and Cooperative Agreements

This policy governs financial conflicts of interest that may arise for grantees and Investigators participating applications and awards of all National Institutes of Health (NIH) grants and cooperative agreements, excluding the Phase I Small Business Initiative Research (SBIR) and Small Business Technology Transfer (STTR) applications and awards. Under federal law, all institutions whose faculty participate in such grants and cooperative agreements must have a Financial Conflict of Interest (FCOI) policy that complies with the government's regulations. The following policy is effective September 16, 2022 (see NIH Guide Notice NOT-OD-22-210). Defined terms are capitalized, and reference be made to those definitions as the policy is reviewed.

Disclosure, Review and Monitoring

1. NIH requires each institution applying for or receiving a grant or cooperative agreement from the Public Health Service (e.g., National Institutes of Health), to maintain an appropriate written and enforced policy on Financial Conflicts of Interest. Grantees and Investigators (except Phase I SBIR/STTR applicants and/or recipients) are required to comply with the requirements of [Regulation 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for with PHS Funding is Sought."](#)
2. Under this policy, each Investigator¹ following Colby College policy is required to disclose to the Office of Foundation Relations and Sponsored Programs (grants@colby.edu) all Significant Financial Interests of the Investigator related to the Investigator's Institutional Responsibilities (including those of the Investigator's spouse and dependent children). Subrecipient Investigators are required to disclose their SFIs that are related to the subcontract work they are performing for the prime institution (Colby College).
3. A Financial Interest is anything of monetary value, whether or not the value is readily ascertainable. "Significant Financial Interest" refers to a Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities²:
 - a. With regard to any publicly traded entity, a Significant Financial Interest 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

¹ The term "Investigator" means 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 PHS, or proposed for funding by PHS, which may include, for example, consultants or collaborators.

² "Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the University, which may include for example: activities such as Research, Research consultation, teaching, professional practice, University committee memberships, and service on panels such as Institutional Review Boards or data and safety monitoring boards.

- 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;
- b. With regard to any non-publicly traded entity, a Significant Financial Interest 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/domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, private equity or other ownership interest) or venture or capital financing in a company with which the Investigator has a Financial Interest;
 - c. Intellectual property rights and interests (e.g., patents, copyrights); or
 - d. The occurrence of any reimbursed or sponsored travel.
4. The following are not Financial Interests and do **not** require disclosure:
- a. 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;
 - b. 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;
 - c. income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, an institution of higher education within the U.S., an academic teaching hospital within the U.S., a medical center within the U.S., or a research institute that is affiliated with an institution of higher education within the U.S.;
 - d. income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, an institution of higher education within the U.S., an academic teaching hospital within the U.S., a medical center within the U.S., or a research institute that is affiliated with an institution of higher education within the U.S.; or
 - e. travel that is reimbursed or sponsored by a U.S. federal, state, or local government agency, an institution of higher education within the U.S., an academic teaching hospital within the U.S., a medical center within the U.S., or a Research institute that is affiliated with an institution of higher education within the U.S.
5. Investigators, including subrecipient Investigators following Colby College's policy, must also disclose all Financial Interests, foreign appointments, foreign-sourced income, and in-kind support, regardless of value, received from:
1. a foreign institution of higher education, including any affiliated Research institutes;
 2. a foreign academic teaching hospital or medical center; and
 3. the government of a foreign country (which includes local, provincial, or equivalent governments of another country).
6. Investigators must provide all required financial disclosures at the time the proposal is submitted to NIH via the **Financial Disclosure Form**. These financial disclosures must also be updated during the period of the award, either on an annual basis, or as new reportable Significant Financial Interests are discovered, whichever occurs first.

7. Prior to the expenditure of any funds under a Public Health Service (PHS)³-funded Research project, designated College officials—including but not limited to the Director of Sponsored Programs—shall, consistent with [§ 50.604\(f\)](#):
 - a. review all Investigator disclosures of Significant Financial Interests;
 - b. determine whether any Significant Financial Interests relate to PHS-funded Research;
 - c. determine whether a financial conflict of interest exists; and, if so,
 - d. develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.
8. A financial conflict of interest exists when College officials responsible for reviewing the disclosures reasonably determine that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded Research, including the Investigator's Significant Financial Interest in an entity whose Financial Interest could be affected by such PHS/NIH-funded Research.
9. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are 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 conflicts 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 the Research;
 - f. reduction or elimination of the Financial Interest (e.g., sale of an equity interest);
or
 - g. severance of relationships that create financial conflicts.The College is required to monitor compliance with any management plan through completion of the project.
10. It is critically important that if a new Significant Financial Interest arises during the course of a Research project, or a new Investigator is added to the project, a new disclosure must be filed. Thus, in the course of an ongoing PHS-funded Research project, when an existing Investigator discloses a new Significant Financial Interest to the College, or when an Investigator who is new to participating in the Research project discloses a Significant Financial Interest, the College shall, within 60 days:
 - a. review the disclosure of the Significant Financial Interest;
 - b. determine whether it is related to PHS-funded Research;
 - c. determine whether a financial conflict of interest exists; and, if so,
 - d. 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 financial conflict of interest.

Depending on the nature of the Significant Financial Interest, the College may determine that additional interim measures are necessary with regard to the Investigator's

³ "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 involved may be delegated, including the NIH.

participation in the PHS-funded Research project between the date of disclosure and the completion of the College's review.

11. In addition, If the College identifies that a Significant Financial Interest was not disclosed timely by an Investigator, or for whatever reason, was not previously reviewed or identified by the College during an ongoing PHS/NIH-funded Research project, the College's designated official shall, within sixty (60) days review the disclosures of the Significant Financial Interests, determine whether the Significant Financial Interest is related to PHS/NIH-funded Research, determine whether a FCOI exists, and if so, implement, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken, to manage the FCOI going forward.

Reporting, Maintenance, & Public Accessibility of Records

12. In cases in which the College identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the College is not required to submit an FCOI report to the PHS Awarding Component.
13. For any significant conflicts of interest discovered during review, the College will submit initial, annual (i.e., ongoing) and revised FCOI reports on behalf of the College and its subrecipients, if applicable, to the NIH via the eRA Commons FCOI Module.
14. FCOI reports will be submitted
 - a. prior to the expenditure of funds
 - b. within 60 days of identification for an Investigator who is newly participating in the project
 - c. within 60 days for new, or newly identified, FCOIs for existing Investigators
 - d. at least annually (at the same time as when the College is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - e. after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review.
15. FCOI reports will 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. A report will include at minimum:
 - a. Project number;
 - b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - c. Name of the Investigator with the FCOI;
 - d. Name of the entity with which the Investigator has a FCOI;
 - e. Nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - f. Value of the Financial Interest (dollar ranges are permissible: \$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;
 - g. A description of how the Financial Interest relates to the NIH-funded Research and why the College determined that the Financial Interest conflicts with such Research;
 - h. A description of the key elements of the College's management plan, including:
 - i. Role and principal duties of the conflicted Investigator in the Research project;
 - ii. Conditions of the management plan

- iii. How the management plan is designed to safeguard objectivity in the Research project;
 - iv. Confirmation of the Investigator's agreement to the management plan;
 - v. How the management plan will be monitored to ensure Investigator compliance; and
 - vi. Other information as needed.
16. In addition, if bias is found, the College will promptly submit a mitigation report (submitted as a "Revised FCOI Report" if the FCOI was previously reported to the NIH). The mitigation report must include, at a minimum,
- a. a description of the impact of the bias on the Research project;
 - b. a plan of action or actions taken to eliminate or mitigate the effect of the bias.
17. The College is required to notify NIH promptly if an Investigator fails to comply with the College's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of PSH/NIH funded Research. It is also required to institute appropriate corrective actions for non-compliance with the College's FCOI policy and for an FCOI management plan that appears to have biased the design, conduct, or reporting of PSH/NIH funded Research.
18. The College will maintain all FCOI-related records relating to all Investigator disclosures of Financial Interests and the review of, and response to, such disclosures (whether or not a disclosure resulted in the College's determination of a financial conflict of interest) and all actions under this policy or retrospective review, if applicable
- a. for at least three (3) years from the date the final expenditures report is submitted to the PHS (NIH).
 - b. or, where applicable, from other dates specified in [45 CFR 75.361](#) for different situations.
19. This policy is publicly accessible on Colby's website.
20. Information concerning identified FCOIs held by senior/key personnel prior to the expenditure of funds will be made available within five (5) business days of a written request. This information will
- a. include the minimum elements required by regulation (see [42 CFR 50.605\(a\)\(5\)\(i\)-\(iv\)](#));
 - b. include any updates since the initial report, including annual updates as well as newly identified FCOI's;
 - c. remain available for three (3) years from the date the information was most recently updated. To the extent that the College's record retention policy imposes a longer period of time, such information will be retained for the time period pursuant to that policy.

Non-Compliance

21. In instances where there is non-compliance with this policy, the College may institute enforcement mechanisms, sanctions and other administrative actions. Such measures may include:
- a. 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;
 - b. modification of the Research plan;
 - c. change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research;

- d. reduction or elimination of the Financial Interest (e.g., sale of an equity interest);
 - e. severance of relationships that create financial conflicts;
 - f. letters of reprimand;
 - g. restrictions on the use of funds;
 - h. withdrawal from/termination of the project for which such funds were used; and/or
 - i. any other measures, sanctions or actions designed to ensure compliance with this policy.
22. Non-compliance includes:
- j. failure by the Investigator to disclose a Significant Financial Interest that is determined by the College to constitute a FCOI;
 - k. failure by the College to review or manage such a FCOI; or
 - l. failure by the Investigator to comply with the FCOI management plan.
23. The College will complete a retrospective review within 120 days of the College's determination for noncompliance to determine whether any NIH-funded Research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such Research. See 42 CFR 50.605(a)(3).
24. A retrospective review will document:
- a. project number
 - b. project title
 - c. Project Director (PD)/Principal Investigator (PI), or contact PD/PI if multiple PD/PI model is used;
 - d. name of the Investigator with the FCOI;
 - e. name of the entity with which the Investigator has an FCOI;
 - f. reasons for the retrospective review;
 - g. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
 - h. findings of the review; and
 - i. conclusions of the review.
25. In addition, if bias is found as part of the retrospective review, the College will promptly submit a mitigation report (submitted as a "Revised FCOI Report" if the FCOI was previously reported to the NIH). The mitigation report must include, at a minimum,
- a. the key elements documented in the retrospective review in (24) above;
 - b. a description of the impact of the bias on the Research project;
 - c. a plan of action or actions taken to eliminate or mitigate the effect of the bias.
26. If the Department of Health and Human Services determines that a PHS/NIH-funded Research 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 the Investigator with an FCOI that was not managed or reported by the College, as required by regulation, the College shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the Research, and request an addendum to previously-published presentations.

Subrecipient Requirements

27. As an awardee institution, the College is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. The College must incorporate as part of a written agreement with a subrecipient terms that establish whether the Financial Conflict of Interest policy of the College or that of the subrecipient will apply to subrecipient

- Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.
28. Subrecipient Institutions who rely on their own Financial Conflict of Interest policy must report identified financial conflicts of interests to the College in sufficient time to allow the College to report the Financial Conflict of Interest to the NIH to meet its reporting obligations.
 29. Subrecipient institutions that must comply with the College's policy must submit all Investigator disclosures of Significant Financial Interests to the College in sufficient time to allow the College to review, manage and report identified FCOIs to the NIH.
 30. The College 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.

Training

31. Each Investigator is required to complete the NIH's Financial Conflict of Interest (FCOI) online training module
 - a. prior to engaging in Research related to any PHS/NIH-funded grant
 - b. at least every four (4) years
 - c. immediately, if:
 - i. the College revises its FCOI policy that affects requirements of Investigators
 - ii. an Investigator is new to the College
 - iii. an Investigator is not in compliance with the policy or management plan.
32. The training module consists of a self-paced tutorial and quiz. The quiz must be taken to obtain a certificate of completion, which must be forwarded to grants@colby.edu.
33. Additional information on this regulation can be found at <https://grants.nih.gov/grants/policy/coi/> and <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=question52888>.

I certify that I have read and understood the information provided in this document.

Print Name Here

Signature

Date: _____

**Financial Disclosure Form for Investigators
Pursuant to Colby College Financial Conflict of Interest (FCOI) Policy
for the National Institutes of Health**

This form must be completed by Investigators¹ who plan to participate in Research² funded, or proposed to be funded, by the National Institutes of Health, including Public Health Services-funded Research. Please answer **all** of the questions. Do **not** leave any questions blank. If a question does not apply to you, simply put "**N/A**" or "**None**" in the box. Once completed, this form should be sent by email to grants@colby.edu for filing. It is also recommended that you save an electronic copy of your completed form for future reference and updates. If the form is associated with a project currently pending, please also let us know in the body of the email to grants@colby.edu.

Investigator Name: _____

Department: _____

Title of Proposal: _____

Project PI: _____

Sponsor: _____

This form asks you to provide information regarding outside financial interests that are or reasonably appear to be related to your Institutional Responsibilities³ at Colby College.

¹ The term "Investigator" means 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 PHS, or proposed for funding by PHS, which may include, for example, consultants or collaborators.

² "Research" means a systematic investigation, study or experiment designed to develop or 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). The term includes any such activity for which research funding is available from a PHS Awarding Component (the organizational unit within PHS that funds the research) through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

³ "Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the University, which may include for example: activities such as research, Research consultation, teaching, professional practice, University committee memberships, and service on panels such as Institutional Review Boards or data and safety monitoring boards.

Significant Financial Interests

1. Have you, your spouse/domestic partner, or your dependent children received any remuneration, gift, or in-kind support, regardless of amount, from a foreign institution of higher education, foreign academic teaching hospital, and/or the government of a foreign country (which includes local, provincial, or equivalent governments of another country)?

Yes No

2. Have you negotiated participation or participated in a Foreign Talent Recruitment Program⁴ by a foreign institution of higher education, foreign academic teaching hospital, and/or the government, at any level, of a foreign country?

Yes No

If you answered yes to question 1 or 2, please provide additional details, including identifying the foreign entity, describing your relationship to it, and including the approximate value of any remuneration received.

Significant Financial Interests in Publicly-Traded Entities

3. Do you, your spouse/domestic partner, or your dependent children have any of the following interests in a publicly-traded entity that, alone or when aggregated, exceeds \$5,000 and that is or reasonably appears to be related to your Institutional Responsibilities at Colby College:

- Remuneration (such as consulting fees, honoraria, or paid authorship) received in the last twelve months
- Equity interest (stock, stock options, or other ownership interest)

Yes No

If yes, please provide details, including the name of the outside entity, the nature of the activity for which remuneration was received, the amount of remuneration received over the last twelve months, the value of any equity interest as of the date of this disclosure (as determined through reference to public prices or other reasonable measures of fair market value), the percentage of ownership interest in the outside entity, and the manner in which the equity interest was acquired.

Significant Financial Interests in Non-Publicly-Traded Entities

4. Have you, your spouse/domestic partner, or your dependent children received from a non-publicly traded entity over the last twelve months any remuneration (such as consulting fees, honoraria, or paid authorship) that alone, or when aggregated, exceeds \$5,000 and that is or reasonably appears to be related to your Institutional Responsibilities at Colby College? (A

⁴ Foreign Talent Recruitment Program: means any program sponsored by, or benefit offered (whether in the form of remuneration or in-kind support) by a foreign Researcher, foreign government (at any level), foreign institution, or foreign government-controlled entity for the purpose of facilitating the transfer or acquisition of expertise, technical know-how, Research results/data/designs, or technology. These programs may involve entering into a contract with a foreign institution or entity and may be accompanied by an honorary, adjunct, or temporary appointment.

non-publicly-traded entity may be for-profit, non-profit, or governmental, but does not include Colby College.)

Yes No

If yes, please provide details, including the name of the outside entity, the nature of the activity for which payment was received, and the amount of the remuneration received over the last twelve months.

5. Do you, your spouse/domestic partner, or your dependent children hold, in a non-publicly traded entity, any equity interest (e.g., stock, stock option, or other ownership interest) that is or reasonably appears to be related to your Institutional Responsibilities at Colby College? (Please note that this question applies to any equity interest, regardless of value.)

Yes No

If yes, please provide details, including the name of the outside entity, the dollar value and percentage of ownership interest in the outside entity, and the manner in which the equity interest was acquired.

Intellectual Property Rights and Interests.

6. Do you, your spouse/domestic partner, or your dependent children have any intellectual property rights and interests (e.g., patents and copyrights) from which you or they have received any related income in the last twelve months and that are or reasonably appear to be related to your Institutional Responsibilities at Colby College? (Please note that this question applies regardless of the value of the income received. You need not disclose intellectual property rights assigned to Colby College and agreements to share in royalties related to such rights.)

Yes No

If yes, please provide details, including the nature of the intellectual property rights and interests, how they were acquired, and the amount of income received.

Reimbursed or Sponsored Travel.

7. Please disclose any reimbursed or sponsored travel by you, your spouse/partner, and your dependent children, regardless of value that occurred in the last twelve months and that is or reasonably appears to be related to your Institutional Responsibilities at Colby College. (You need not disclose travel that is reimbursed or sponsored by Colby College, 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.)
- What was the purpose of the trip?
 - What is the name of the organization that reimbursed or sponsored the travel?
 - What was the destination of the trip?
 - What was the duration of the trip?

Federally-Funded Proposals or Awards

8. Do you believe that any of the Significant Financial Interests you described in response to Questions (1)-(5) relate to any federally funded proposal or award on which you are an Investigator? Please explain.

Note: A Significant Financial Interest relates to federally-funded Research if (a) the Significant Financial Interest could directly and significantly affect (that is, it would have a material impact on) the design, conduct, or reporting of the PHS/NIH-funded research, or (b) the Significant Financial Interest is in an entity whose financial interest could be affected by the Research.

I certify that all of the foregoing information in this form is true and complete to the best of my knowledge. I acknowledge that, during the period of a federally-funded award, I am required to update this form annually and within 30 days of discovering or acquiring a new Significant Financial Interest.

Signature

Date

Full Name (Printed)

Position Title