

Procedures for Complying with the Financial Conflicts of Interest Requirements of the Public Health Service (PHS)

PART A: Web Site

Augustana College policy and procedures related to financial conflicts of interest (FCOI) are located on the web site at <https://www.augustana.edu/about-us/offices/business/sponsored-research-policies>

PART B: Notification

Every January, the Business Office will inform each Principal Investigator (PI) and co-Investigator on PHS-funded research projects concerning the Policy on Conflicts of Interest in Externally Funded Projects, their responsibilities regarding disclosure of significant financial interests (SFI) as defined in Part F of these procedures, and the PHS regulations at 42 CFR 50/45 CFR 94, as applicable. The notice will indicate that each Investigator will also be required to complete training regarding FCOI prior to engaging in research related to any PHS-funded award, every four years while the project is active, and immediately when any of the following circumstances apply: (1) AUGUSTANA COLLEGE revises its FCOI policies or procedures in any manner that affects the requirements of PHS-funded Investigators; (2) a PHS-funded Investigator is new to AUGUSTANA COLLEGE; or (3) AUGUSTANA COLLEGE finds that a PHS-funded Investigator is not in compliance with AUGUSTANA COLLEGE's FCOI policy or management plan. The notice will state that the PI should contact the Controller if there are any key personnel on the PHS-funded project who are not listed as co-Investigators. The notice will direct PIs and co-Investigators to on how to make or update the disclosure required in Part F of these procedures. The notice will state that any changes in SFI previously reported must be updated as they occur (within 30 days) during the life of the project.

A similar notice will be distributed to PIs and co-Investigators at the time the Business Office is made aware of a PHS proposal for funded research.

PART C: Training

Investigators for whom FCOI training is mandated by PHS requirements must complete such training prior to participation in PHS-funded research and every four years thereafter as long as the project is active. This educational requirement is met by completing the NIH Conflicts of Interest Tutorial course located on the NIH Website at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html Once Investigators have successfully completed the course they should print a completion certificate for their own records and submit a copy of the certificate as outlined in the training notice. The Business Office will monitor compliance with this mandatory training requirement.

PART D: Subcontracts Under PHS Awards

Subcontracts under PHS awards will specify whether the FCOI policy of AUGUSTANA COLLEGE or that of the subrecipient will apply to the subrecipient's Investigators/key personnel. If the subrecipient's policy applies, the subrecipient will be required to certify as part of the subcontract that its policy complies with applicable PHS FCOI regulations and the subcontract will specify time period(s) for the subrecipient to report all identified FCOI to AUGUSTANA COLLEGE. Alternatively, if the subrecipient's Investigators must comply with AUGUSTANA COLLEGE's FCOI policy, the subcontract will specify time period(s) for the subrecipient to submit all Investigator disclosures of SFI to AUGUSTANA COLLEGE. In either case, the time period(s) specified must be sufficient to enable AUGUSTANA COLLEGE to comply timely with its review, management, and reporting obligations under applicable PHS FCOI regulations.

PART E: Institutional Official

The Provost is the institutional official designated to review disclosures of SFI (as described in Part F of these procedures) from each Principal Investigator, co-Investigator or key personnel who is planning to participate in, or is participating in, PHS-funded research.

PART F: SFI Disclosure and FCOI Determination

AUGUSTANA COLLEGE employees who participate in the design, conduct, and/or reporting of PHS-funded research as Principal Investigators (PIs), co-Investigators, or key personnel—hereinafter called “Investigators”—are required to disclose, on behalf of themselves, their spouses, and their dependent children, *first*, whether they have any Significant Financial Interest that would reasonably appear to be related to their institutional responsibilities, and, *second*, if so, what those interests are.

Significant Financial Interest (SFI) means either (1) or (2) below:

(1) 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*:

(i) 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 completion of this questionnaire and the value of any equity interest in the entity as of the date of completion of this questionnaire, 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;

(ii) 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 completion of this questionnaire, 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

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests in excess of \$5,000, and/or when the value of these rights and interests is determined by Augustana College to be in excess of \$5,000.

(2) Any reimbursed or sponsored travel in excess of \$5,000 (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), *related to their institutional responsibilities*, but excluding travel that is reimbursed or sponsored by (i) a Federal, state, or local government agency, (ii) an institution of higher education, or (iii) an academic teaching hospital, medical center, or research institute that is affiliated with an institution of higher education.

SFI does *not* include the following types of financial interests:

- salary, royalties, or other remuneration paid by AUGUSTANA COLLEGE to the Investigator if the Investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university 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 located in the United States, an institution of higher education (IHE) located in the United States, 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.

Investigator Disclosure Procedure

PIs will inform the Business Office of all Investigators on their projects. The Business Office will send an email with an attached SFI Questionnaire (PHS) to each Investigator. Returned questionnaires with a “No” response will be filed in the grant folder. If a returned questionnaire has a “Yes” response, the Business Office will promptly send an SFI Disclosure (PHS) form for the Investigator to complete and return.

Significant Financial Interests Disclosure Form (PHS)

Completed questionnaires with a “No” response will be reviewed by the Controller. Completed questionnaires with a “Yes” response and completed disclosure forms will be reviewed by the Provost. After reviewing the information disclosed, the Provost will make the following determination:

Whether either (a) the SFI could be affected by the proposed project, or (b) the SFI is in an entity whose financial interest could be affected by the project.

The Provost may consult with the Investigator in making this determination. If the determination is “Yes” for either (a) or (b), a potential financial conflict of interest (FCOI) will be deemed to exist. The Controller, in conjunction with relevant Academic Affairs staff, will need to coordinate the development and implementation of an FCOI Management Plan (see Part G) prior to the expenditure of any funds under the proposed project.

PART G: Managing FCOI

The Controller will coordinate the development of any FCOI management plan that may be required under these procedures. Such coordination will involve at least consultation with the Provost and the individual found to have the potential FCOI. Management plans will be structured to ensure that the disclosed SFI will not affect the design, conduct, or reporting of the PHS-funded research and will address, at a minimum, the following:

- 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; and
- How the management plan will be monitored to ensure Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a potential FCOI include, but are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the potential FCOI;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses an SFI or an existing Investigator discloses a new SFI to AUGUSTANA COLLEGE, the Provost will, within sixty days: review the disclosure of the SFI; determine whether it is related to PHS-funded research; determine whether a potential FCOI exists; and, if so, implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage such potential FCOI. Depending on the nature of the SFI, AUGUSTANA COLLEGE may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of AUGUSTANA COLLEGE's review.

Whenever AUGUSTANA COLLEGE identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by AUGUSTANA COLLEGE during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Provost will, within sixty days: review the SFI; determine whether it is related to PHS-funded research and so represents a potential FCOI; and, if needed, implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage such potential FCOI going forward.

In addition, whenever a potential FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined by AUGUSTANA COLLEGE to constitute a potential FCOI; failure by AUGUSTANA COLLEGE to review or manage such a potential FCOI; or failure by the Investigator to comply with an FCOI management plan), AUGUSTANA COLLEGE will, within 120 days of AUGUSTANA COLLEGE's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

AUGUSTANA COLLEGE will document the retrospective review. Such documentation will include, but not necessarily be limited to, all of the following key elements:

- Project title and other identifying details;
- Principal Investigator;
- Name of the Investigator with the potential FCOI;
- Name of the entity with which the Investigator has a potential 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.

Based on the results of the retrospective review, if appropriate, AUGUSTANA COLLEGE will update the previously submitted FCOI report (see Part H), specifying the actions that will be taken to manage the potential FCOI going forward. If bias is found, AUGUSTANA COLLEGE will notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and AUGUSTANA COLLEGE's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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, AUGUSTANA COLLEGE will submit FCOI reports annually. Depending on the nature of the potential FCOI, AUGUSTANA COLLEGE may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the potential FCOI or the Investigator's noncompliance is determined and the completion of AUGUSTANA COLLEGE's retrospective review.

Whenever AUGUSTANA COLLEGE implements an FCOI management plan, AUGUSTANA COLLEGE will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to AUGUSTANA COLLEGE's expenditure of any funds under a PHS-funded research project, AUGUSTANA COLLEGE will ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any SFI disclosed to AUGUSTANA COLLEGE that meets the following three criteria: (A) The SFI was disclosed and is still held by the Investigator; (B) AUGUSTANA COLLEGE determines that the SFI is related to the PHS-funded research; and (C) AUGUSTANA COLLEGE determines that the SFI is a potential FCOI.

The information that AUGUSTANA COLLEGE makes available, via written response to any requestor within five business days of a request, will include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI, 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.

AUGUSTANA 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 AUGUSTANA COLLEGE's identification of a new potential FCOI, which should be requested subsequently by the requestor.

Information concerning disclosed SFI will remain available for responses to written requests for at least three years from the date that the information was most recently updated.

PART H: Reporting to PHS

Initial Reports

Prior to AUGUSTANA COLLEGE's expenditure of any funds under a PHS-funded research project, AUGUSTANA COLLEGE will provide to the PHS awarding component an FCOI report regarding any Investigator's SFI found by AUGUSTANA COLLEGE to be conflicting and ensure that AUGUSTANA COLLEGE has implemented a management plan in accordance with these procedures. In cases in which AUGUSTANA COLLEGE identifies a potential FCOI and eliminates it prior to the expenditure of PHS-awarded funds, no report is required. In addition, AUGUSTANA COLLEGE will report to the PHS awarding component any FCOI of a subrecipient Investigator prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

For any SFI that AUGUSTANA COLLEGE identifies as conflicting subsequent to AUGUSTANA COLLEGE's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), AUGUSTANA COLLEGE will provide to the PHS awarding component, within sixty days, an FCOI report regarding the potential FCOI and ensure that AUGUSTANA COLLEGE has implemented a management plan in accordance with these procedures. If an FCOI report involves an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by AUGUSTANA COLLEGE (e.g., was not timely reviewed or reported by a subrecipient), AUGUSTANA COLLEGE will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the potential FCOI was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, AUGUSTANA COLLEGE will notify the PHS awarding component promptly and submit a mitigation report.

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 AUGUSTANA COLLEGE's management plan. Elements of the FCOI report will include, but are not necessarily limited to, the following:

- Project number;

- Principal Investigator;
- Name of the Investigator with the potential FCOI;
- Name of the entity with which the Investigator has a potential FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest 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;
- A description of how the financial interest relates to the PHS-funded research and the basis for AUGUSTANA COLLEGE's determination that the financial interest conflicts with such research; and
- A description of the key elements of AUGUSTANA 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.

Annual Reports

For any potential FCOI previously reported by AUGUSTANA COLLEGE with regard to an ongoing PHS-funded research project, AUGUSTANA COLLEGE will provide to the PHS awarding component an annual FCOI report that addresses the status of the potential FCOI 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 potential FCOI no longer exists. AUGUSTANA 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.

PART I: Maintaining Records

The Business Office will maintain records relating to all Investigator disclosures of financial interests and AUGUSTANA COLLEGE's review of, and response to, such disclosures (whether or not a disclosure resulted in AUGUSTANA COLLEGE's determination of a potential FCOI), and all actions under these procedures, for at least three years from the date the final expenditure report is submitted to PHS or, where applicable, from other dates specified in 45 CFR 75.361 and 92.42 (b) for different situations.

PART J: Enforcement Mechanisms

AUGUSTANA COLLEGE anticipates that Investigators will comply fully and promptly with the FCOI policy and these procedures. Examples of non-compliance include, but are not limited to:

- failure to submit required statements or updates;
- failure to provide additional information requested by the Business Office or the Provost;
- knowingly filing an incomplete, erroneous or misleading SFI Questionnaire or SFI Disclosure;
- failing to comply with conflict of interest management plans; or
- knowingly violating applicable laws or regulations.

Non-compliance may result in disciplinary action and/or sanctions. Examples of possible sanctions include formal reprimand; non-renewal of appointment; termination of appointment for good cause; and/or any other enforcement action mandated by the sponsoring agency.

The Provost is responsible for investigating instances of non-compliance and making recommendations regarding possible sanctions to the provost. In making these investigations, he/she may consult with the applicable department chair, or other appropriate individuals.

If the failure to comply has resulted in a bias of the design, conduct or reporting of PHS-sponsored research, the Provost will take appropriate corrective actions and promptly notify the PHS awarding component of corrective actions to be taken.

An Investigator who is the subject of a disciplinary action may appeal such action in accordance with established university faculty or staff grievance and/or disciplinary procedures, as applicable.

PART K: Certification in Applications for PHS Funding

Following these procedures will allow the designated university official to certify, in each application for funding to which 42 CFR 50 or 45 CFR 94 applies, that AUGUSTANA COLLEGE: (1) Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from the PHS; (2) Will promote and enforce Investigator compliance; (3) Will manage FCOI and provide initial and ongoing FCOI reports to the PHS awarding component as required; (4) Agrees to make information available, promptly upon request, relating to any Investigator disclosure of SFI and AUGUSTANA COLLEGE's review of, and response to, such disclosure, whether or not the disclosure resulted in the determination of a potential FCOI; and (5) Will fully comply with applicable PHS FCOI requirements.