Title:	**Financial Conflict of Interest (FCOI) Policy**
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1. PURPOSE AND INTRODUCTION

Frontier Science Foundation is committed to conducting research with high scientific and ethical standards. The purpose of the Financial Conflict of Interest (FCOI) Policy is to document the requirements and responsibilities of Frontier Science to promote objectivity in research. Frontier Science has established standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. The FCOI Policy describes the compliance and reporting requirements of Frontier Science and its Investigators.

2. SCOPE

The FCOI Policy applies to Frontier Science Investigators applying for or receiving PHS research funding and any other employee, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research.

3. TERMINOLOGY

Term	Definition
Financial conflict of interest (FCOI)	A significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
Financial interest	Anything of monetary value, whether or not the value is readily ascertainable.
Institution	Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
Investigator	The Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include collaborators, consultants, or subrecipients.
Manage	An action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
National Institutes of Health (NIH)	A Federal agency whose mission is to improve the health of the people of the United States. NIH is a part of the Public Health Service, which is part of the U.S. Department of Health and Human Services.
Public Health Service (PHS)	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 National Institutes of Health (NIH).
Research	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

Term	Definition
	Component through a grant or cooperative agreement, 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.
Significant financial interest (SFI)	(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, 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 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, 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 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. (2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (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; 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 PHS-funded research. (3) 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

Term	Definition
	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; or 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.
Subrecipient	A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants.

4. ROLES AND RESPONSIBILITIES

Role	Responsibilities
Designated official	Solicits, reviews, evaluates, and addresses disclosures of SFIs from Investigators and determines if an FCOI exists. Takes action to manage the FCOI.
Institution	Creates and maintains an up-to-date written and enforced FCOI policy and makes it publicly accessible. Informs the Investigator of the regulation and FCOI policy, the Investigator's responsibilities regarding disclosure of SFI, and requires each Investigator to complete training prior to engaging in PHS-funded research. Provides guidelines for the designated official to identify an FCOI.
Investigator	Completes all required training, discloses all SFI relating to PHS, mitigates risks associated with SFI, and assists with the management of any identified SFI.

5. TRAINING

The Investigator must complete training on the regulation, the FCOI policy, and the responsibility to disclose any Significant Financial Interests (SFIs). Training must be completed prior to participating in PHS-funded research and again at least every four years. Training must also be completed immediately if Frontier Science revises its FCOI policy or procedures in any way that affects the Investigator requirements, if an Investigator is new to Frontier Science, or if Frontier Science finds that an Investigator is not in compliance with the FCOI policy or management plan.

Training consists of reviewing the FCOI Policy and successfully completing the NIH FCOI Tutorial online course located on the NIH website, entitled “Financial Conflict of Interest (FCOI) Office of Extramural Research (OER) National Institutes of Health (NIH).”

6. DISCLOSURE

The Investigator must disclose any SFI prior to applying for or initiating work on PHS-funded research, within 30 days of any new SFI (including acquisition due to marriage, purchase, or inheritance), and annually to update disclosed SFI information (e.g., a change in the value of a previously disclosed interest). A disclosure request is distributed annually by email and the disclosure form remains accessible throughout the year through a designated online form. The disclosure must include SFIs of the Investigator, spouse, and dependent children. The disclosure must include SFIs that reasonably appear to be related the Investigator’s Frontier Science responsibilities. An SFI is defined in the Terminology section, and generally occurs when the Investigator receives remuneration from a conflicted entity within a twelve month period and which when aggregated exceeds $5,000. If, after the submission of an annual disclosure, there is a material change in an Investigator’s SFI, the disclosure should be updated immediately in writing to reflect the change.

7. REVIEW AND MONITORING

SFI disclosures are reviewed by the designated official; the Frontier Science designated official is the Chief Operating Officer. The designated official reviews within 60 days of receiving the SFI disclosure. If a determination that an FCOI may exist is made, Frontier Science appoints an executive committee to verify the determination of the designated official, and the Investigator will not participate in the PHS-funded research until the review is complete and a determination is made.

If an FCOI exists, Frontier Science provides a written management plan to specify actions to address the FCOI.

1. If it is determined that an SFI exists, Frontier Science responds by eliminating, reducing, or managing the conflict in accordance with 42 CFR Part 50 Subpart F or 45 Subchapter-A Part 94.4. Frontier Science completes a retrospective review and generates a written record of its response, provides a written copy of the management plan to the Investigator, and the Investigator must sign the management plan indicating receipt, comprehension, and willingness to fully comply. The management plan to eliminate, reduce, or manage the FCOI is reviewed at least annually to determine if it needs updating, and to verify Investigator compliance with the management plan.
2. A conflict can be eliminated by requiring that the Investigator divest the financial interest, or not participate in the conflicting activity. The Investigator may be required to reduce this financial interest to a level that Frontier Science determines is acceptable for the activity in question. In some cases, a conflicted activity may be allowed to proceed with a credible management plan to address the conflict in a way that acceptably minimizes the associated risks (e.g., by a change of personnel, a change of a person’s role and responsibilities related to certain activities, modification of the research plan, or having a person refrain from participation in all or part of the activity).

8. REPORTING

Frontier Science submits FCOI reports through the electronic Research Administration (eRA) Commons FCOI Module, in accordance with 42 CFR 50.605(b)(3) or 45 CFR 94.5(b)(3). On request, Frontier Science also provides Investigator disclosures, reviews, and responses to the PHS.

If there is a determination an FCOI exists, it is published prior to the expenditure of funds, within sixty (60) days of its determination, and updated annually.

Frontier Science provides the following FCOI Reports:

Report	Content	When Required
Initial FCOI report	Project number, PD/PI, name of Investigator with the FCOI, name of entity with which the Investigator has an FCOI, nature of the financial interest, value of the financial interest, description of how the financial interest relates to the PHS-funded research and the basis for the FCOI determination, and key elements of management plan.	Prior to expenditure of funds and within 60 days of any subsequently identified FCOI.
Annual FCOI report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and changes to the management plan, if applicable.	When submitting an annual progress report, multi-year progress report, or at the time of an extension.
Revised FCOI report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage an FCOI going forward or make changes to an originally submitted FCOI report.	As needed, following the completion of a retrospective review when there is noncompliance.
Mitigation report	Project number, project title, PD/PI, name of Investigator with FCOI, name of the entity with which the Investigator has an FCOI, reason for retrospective review, detailed methodology of the review process, findings, and conclusions.	When a bias is found as a result of a retrospective review due to noncompliance.

9. MAINTENANCE OF RECORDS

Frontier Science maintains records relating to Investigator disclosures of an SFI and Frontier Science's review of, and response, to such disclosures (whether or not a disclosure resulted in Frontier Science's determination of an FCOI) and all actions under the FCOI policy or retrospective review, if applicable, for a minimum of three years from the date the final expenditures report is submitted to the PHS or, if applicable, from other dates specified in 45 CFR 75.361 for different situations.

10. ENFORCEMENT AND NONCOMPLIANCE

If the Investigator fails to comply with the FCOI policy or management plan, Frontier Science completes a retrospective review of the Investigator's activities related to the PHS-funded research within 120 days, to determine if a bias existed. Frontier Science will promptly notify the PHS if it is determined the noncompliance resulted in bias of the design, conduct, or reporting. If a bias is determined to exist, Frontier Science may also require that the Investigator disclose this fact in any public presentations relating to the research, and to request an addendum to any previously published presentations.

Willful failure of the Investigator to fully comply with the FCOI policy, including willfully providing materially incomplete or inaccurate disclosures, failure to adhere to the management plan, and/or failure to provide

disclosure in a timely manner may result in disciplinary action. Disciplinary action may include restricting the use of funds, up to, and including, termination of employment.

Frontier Science follows the steps below for FCOI reporting and FCOI noncompliance:

Step	Description
FCOI report	When an SFI is identified that was not previously disclosed, identified, reviewed or managed, the designated official will, within 60 days of identification, review and make the determination of an FCOI, and if it exists, report the FCOI to the PHS.
Retrospective review	If an FCOI exists, complete and document a retrospective review within 120 days of Frontier Science's determination of noncompliance to determine if there was bias in the design, conduct, or reporting of the PHS-funded research. Implement a management plan that specifies the actions that have been, and will be, taken to manage the FCOI going forward.
Update FCOI report	If appropriate, update the existing FCOI report following a retrospective review to specify the actions that have been, and will be, taken to manage the FCOI going forward.
Mitigation report	If bias is found, notify the PHS promptly after retrospective review and submit a mitigation report through the eRA Commons FCOI Module.
Annual FCOI report	Submit an annual FCOI report through the eRA Commons FCOI Module.

11. SUBRECIPIENT

Frontier Science incorporates terms in written subrecipient agreements to elect whether the subrecipient Investigator follows the Frontier Science FCOI policy or the subrecipient FCOI policy. The subrecipient is either required to certify that it has an FCOI policy that complies with the regulation or that the subrecipient follows the Frontier Science FCOI policy. If the latter, the subrecipient agreement includes a requirement for the subrecipient to disclose subrecipient Investigator SFI directly related to the subrecipient's work for Frontier Science, along with specified reporting time periods, to enable Frontier Science to review, manage, and report identified FCOIs to the PHS.

12. PUBLIC ACCESSIBILITY

The FCOI policy is publicly accessible on the Frontier Science website. Identified FCOIs held by Investigators are made publicly accessible prior to the expenditure of funds and for three years from the most recent update. This will include 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.

13. REFERENCES

Document	ID	Location
“Promoting Objectivity in Research”	42 CFR Part 50 Subpart F	Electronic Code of Federal Regulations
“Management and reporting of financial conflicts of interest”	42 CFR 50.605(b)(3)	Electronic Code of Federal Regulations
“Responsibilities of Institutions regarding Investigator financial conflicts of interest”	45 Subchapter-A Part 94.4	Electronic Code of Federal Regulations
“Management and reporting of financial conflicts of interest”	45 CFR 94.5(b)(3)	Electronic Code of Federal Regulations
Final Rule	N/A	Federal Register
Financial Conflict of Interest (FCOI) Office of Extramural Research (OER) National Institutes of Health (NIH)	N/A	NIH FCOI Tutorial
Section 4.1.10 Financial Conflict of Interest	N/A	NIH Grants Policy Statement

14. ATTACHMENTS

None