

	Policy Number:	FCOI Policy v001.001
	Effective Date:	08.28.2017
Policy Title:	Financial Conflicts of Interest In U.S. Public Health Service Funded Research	

I. PURPOSE AND SCOPE OF POLICY

This Policy implements Financial Conflicts of Interest (FCOI) disclosure requirements applicable to Research funded by the U.S. Public Health Service (PHS). The requirements are set forth in 42 CFR Part 50 and 45 CFR Part 94 and are hereinafter referred to as the “PHS FCOI Regulations.” As a condition for receiving PHS funding, these regulations require Pfenex Inc. (“Company”) to maintain an appropriate written policy on financial conflict of interest disclosure. These requirements are applicable to all Research projects for which Company submits a proposal to or receives Research funding from PHS. Each Investigator who is planning to participate in, or is participating in such Research, must follow the relevant sections of these PHS FCOI Regulations. In addition, subcontractors/consultants who perform services within the definition of an Investigator must maintain a policy that complies with the aforementioned PHS FCOI Regulations or comply with this Policy.

The PHS FCOI Regulations and this Policy are intended to promote objectivity in PHS funded Research projects by establishing standards that provide a reasonable expectation that the research will be free from bias resulting from Investigator FCOIs. In particular, the regulations and this Policy establish a process under which Investigators disclose Significant Financial Interests (SFI) to a designated Company official. If Company determines that such an interest could affect the Research directly and significantly, then there is an FCOI and Company will develop a mitigation plan to manage or eliminate the conflict.

II. DEFINITIONS

A. Financial Conflict of Interest

A Financial Conflict of Interest (FCOI) is a SFI that could directly and significantly affect the design, conduct or reporting of PHS funded Research.

B. Investigator

An Investigator is any individual responsible for the design, conduct, or reporting of Research funded by the PHS. This includes the Principal Investigator (PI), Co-Investigators, consultants, subcontractors, and any other individual, regardless of title or position, who is responsible for designing, conducting, or reporting of this Research. For purposes of this definition, an individual is “responsible” for the design, conduct or reporting of Research if he or she has been assigned to oversee or perform a task that could have a significant effect on the design, conduct or reporting of the Research. The Institutional Official will maintain a list of all employees who meet the definition of an Investigator and ensure that such employees are aware of their responsibilities under this Policy.

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C. Institutional Official (IO)

An official designated by Company to solicit and review completed SFI disclosure forms (“Disclosure Forms”) from each Investigator who is planning to participate in, or who is participating in, PHS funded Research and to determine whether any reported SFI is a FCOI. References to the IO in this document include his/her delegate.

D. Institutional Responsibilities

Institutional Responsibilities means an Investigator's professional responsibilities performed on behalf of Company.

E. PHS Awarding Component

PHS Awarding Component means the organizational unit of the PHS that funds the Research.

F. Research

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 as well as product development (e.g., a diagnostic test or drug).

G. Senior/Key Staff

Senior/Key staff means the PI and any other person identified as Senior/Key staff by Company in the grant application, proposal or any other report submitted to the PHS Awarding Component.

H. Significant Financial Interest

Significant Financial Interest (SFI) that must be disclosed in accordance with Section III below means either of the following:

1. Any interest of the Investigator, his/her spouse, and dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities, including, but not limited to, one or more of the following:
 - a. With regard to any publicly traded entity, a 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) and 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;

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- b. With regard to any non-publicly traded entity, a 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
- c. 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.

Note: The term SFI does not include the following types of financial interests:

Salary, royalties, or other remuneration paid by Company to the Investigator or any ownership interest in the Company held by the Investigator if the Investigator is currently employed or otherwise appointed by Company, including intellectual property rights assigned to Company and agreements to share in royalties related to such rights;; income from investment vehicles, such as mutual funds and retirement accounts, provided 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.

III. SFI DISCLOSURE REQUIREMENT

Within three business days of a Company decision to submit a proposal for a PHS funded Research opportunity, the individual with overall responsibility for the proposal effort (the "Proposal Manager") must inform the IO of the decision. The IO will ensure that all Company employees who may serve as Investigators submit SFI Disclosure Forms to the IO not later than 30 calendar days prior to the due date for the proposal. Each Investigator must do so by

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completing the Disclosure Form provided by the IO. The IO will review the Disclosure Forms and notify the Proposal Manager and the Legal Department within three business days of any FCOIs. Within two business days of identification of an FCOI, the IO and the Proposal Manager will confer with the Legal Department to develop an appropriate plan for avoiding or mitigating the conflict.

Additionally, each Investigator is required to submit an updated Disclosure Form to the Company IO within 30 days of discovering or acquiring a new SFI, or at least on an annual basis on the date of the previous disclosure. If an Investigator does not have any SFIs to report, the Investigator must still complete the Disclosure Form annually. Company shall ensure applicable staff complies with these disclosure obligations. Failure to comply with these disclosure obligations may result in disciplinary action by Company.

IV. REVIEW OF DISCLOSURES AND MANAGEMENT OF FCOIS

A. Initial Review Requirement

Prior to Company's expenditure of any funds under a PHS funded Research project, the Company IO will review all Disclosure Forms with SFIs to determine whether the SFIs relate to the PHS funded Research and, if so related, whether a FCOI exists. An Investigator's SFI is related to PHS-funded Research when the IO reasonably determines that the SFI could be affected by the PHS funded Research or is in an entity whose financial interest could be affected by the Research. If a FCOI exists, the Company IO will develop and implement a management plan that specifies the actions that have been, and will be, taken to manage such FCOI.

B. Review of New SFIs

Whenever, in the course of an ongoing PHS funded Research project, (1) an Investigator who is new to participating in the Research project discloses a SFI; (2) an existing Investigator discloses a new SFI; or (3) Company identifies a SFI that was not disclosed timely by an Investigator or was not previously reviewed by Company during an ongoing PHS funded Research project, the Company IO within sixty days of the disclosure will review the SFI to determine whether it is related to PHS funded Research and whether a FCOI exists and, if a FCOI exists, develop and implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, Company 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 Company's review.

C. Management of FCOI

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Examples of conditions or restrictions that may be imposed to manage a FCOI include, but are not limited to the follow actions:

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

D. Retrospective Reviews

Whenever a FCOI is not identified, disclosed or managed in a timely manner or an Investigator fails to comply with a FCOI management plan, Company has additional review and reporting obligations. If in these situations Company determines that a SFI constitutes a FCOI, Company's IO will, within 120 days of Company'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. Company is required to document the retrospective review. Documentation shall include all of the following key elements:

- Project number;
- Project title;
- PI or contact PI if a multiple PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a 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.

As necessary, based on the results of the retrospective review, Company will update any FCOI report previously submitted to the government in accordance with Section V below, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Company will notify the PHS Awarding Component promptly and submit a

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mitigation report to the PHS Awarding Component. Minimally, the mitigation report must include the key elements documented in the retrospective review, a description of the impact of the bias on the Research project, and Company '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, Company will submit FCOI reports annually. Depending on the nature of the FCOI, Company 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 FCOI or the Investigator's noncompliance is determined and the completion of Company's retrospective review.

E. Monitoring

Whenever Company implements a management plan, Company will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS funded Research project.

V. REPORTING OF FINANCIAL CONFLICTS OF INTEREST

A. Initial FCOI Report

Prior to Company 's expenditure of any funds under a PHS funded Research project, Company will provide to the PHS Awarding Component a FCOI report regarding any Investigator's SFI found by Company to be a FCOI. Additionally, Company will ensure that it has implemented a management plan in accordance with Section IV of this Policy. In situations in which Company identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, Company is not required to submit a FCOI report to the PHS Awarding Component.

B. Subsequent FCOI Reports

For any SFI that Company identifies as a FCOI after Company's initial report during an ongoing PHS funded Research project, Company will provide to the PHS Awarding Component a FCOI report regarding the FCOI within 60 days of identification of the FCOI. Additionally, Company will ensure that it has implemented a management plan in accordance with Section IV of this Policy and, if required, complete a retrospective review and a mitigation report according to Section IV of this Policy.

C. Contents of a FCOI Report

Any FCOI report required under Section V will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI and to assess the appropriateness of Company's management plan. The FCOI report will include the following minimum information:

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- Project number;
- PI or Contact PI if a multiple PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- 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 readily be 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 Company’s determination that the financial interest conflicts with such Research; and
- A description of the key elements of Company’s management plan including the following minimum information:
 - Role and principal duties of the conflicted Investigator in the Research project;
 - Conditions of the management plan;
 - Explanation of how the management plan is designed to safeguard objectivity in the Research project;
 - Confirmation of the Investigator's agreement to the management plan; and
 - Explanation of how the management plans will be monitored to ensure Investigator compliance.

D. Annual FCOI Report

For any FCOI previously reported by Company regarding an ongoing PHS funded Research project, Company will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the 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 FCOI is still being managed or explain why the FCOI no longer exists. Company will provide any required 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.

E. Legal Department Review Required

The Company Legal Department must review and approve all FCOI reports prior to submission to the PHS Awarding Component.

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VI. ENFORCEMENT

If the failure of an Investigator to comply with this Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS funded Research, Company is required to promptly notify the PHS Awarding Component of the corrective action taken or to be taken by Company. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Company for further action, which may include directions to Company on how to maintain appropriate objectivity in the PHS funded Research project. Sponsors may impose special award conditions or may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable federal regulations on disclosure, review, and management of SFI related to federally sponsored projects. Failure by Company staff to comply with this Policy may be grounds for disciplinary action up to and including termination.

VII. RECORD RETENTION

Records regarding Disclosure Forms, determinations made by Company's IO, and Company's actions regarding management of a FCOI will be retained by Company for three years beyond the date of the final expenditure report submitted to the PHS Awarding Component under an award or, where applicable, from other dates specified in 48 CFR 4.7, 45 CFR 74.53(b) and 45 CFR 92.42(b).

VIII. TRAINING

Each Investigator must complete a Company FCOI training prior to engaging in PHS funded research. Additionally, Investigators must repeat the training at least every four years and must immediately complete training under the following circumstances:

- Company's FCOI policy changes in a manner that affects Investigator requirements;
- An Investigator is new to Company; or
- Company determines that an Investigator is not in compliance with Company's FCOI policy or management plan.

The IO shall provide training certification forms to the Investigators. Investigators shall sign and submit these forms to the IO within five business days of completing the required training.

IX. SUBCONTRACTORS/CONSULTANTS

Subcontractors/consultants who perform services within the definition of an Investigator must certify in their proposal that they are free of FCOIs and maintain a

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policy that complies with the aforementioned regulatory requirements or comply with this Policy. All applicable subcontract/consulting agreements must contain a clause that requires compliance with the applicable federal regulations either through a policy maintained by the subcontractor/consultant or this Policy. Examples of appropriate clauses are shown below.

Financial Conflicts of interest – Compliance with Subcontractor’s Policy

Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50 or 45 CFR Part 94. Subcontractor certifies that it maintains a policy that requires compliance with these requirements. Subcontractor shall report all identified financial conflicts of interests to Company within five business days of discovering the conflict and submit with this report a mitigation plan for Company’s review and approval. Company is under no obligation to approve a mitigation plan. Company reserves the right to terminate this Agreement or require removal of Subcontractor’s employee or lower tier subcontractor as a result of Subcontractor, its employee, or lower tier subcontractor’s financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.

Financial Conflicts of interest – Compliance with Company’s Policy
Subcontractor, its employees and agents agree to comply with the applicable requirements of 42 CFR Part 50 or 45 CFR Part 94. Subcontractor agrees to comply with Company’s Policy on Financial Conflicts of Interest in Public Health Service Funded Research. Subcontractor shall report all identified financial conflicts of interests to Company within five business days of discovering the conflict and submit with this report a mitigation plan for Company’s review and approval. Company is under no obligation to approve a mitigation plan. Company reserves the right to terminate this Agreement or require removal of Subcontractor’s employee or lower tier subcontractor as a result of Subcontractor, its employee, or lower tier subcontractor’s financial conflict of interest. Subcontractor must include this clause in its agreements with any applicable lower tier subcontractors or consultants. Failure to comply with these requirements is a material breach of this Agreement.

X. PUBLIC ACCESSIBILITY

As required by the PHS FCOI regulations, this policy is publicly available on our website at www.pfenex.com.

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Prior to Company's expenditure of any funds under a PHS funded Research project, Company must ensure the public accessibility, via written response to any requestor within five business days of receipt, of information concerning any SFI disclosed to Company that is (a) held by Senior/Key Staff performing services for the project, (b) related to the PHS funded research, and (c) determined by Company to be a FCOI. The FCOI information that shall be provided in response to such requests is set forth below:

- 1) Investigator's name;
- 2) Investigator's title and role with respect to the research project;
- 3) Name of the entity in which the SFI is held;
- 4) Nature of the SFI; and
- 5) Approximate dollar value of the SFI (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 references to public prices or other reasonable measures of fair market value.

Written responses to requests shall include a note 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 Company's identification of a new financial conflict of interest, which should be requested subsequently by the requestor. Information provided in response to such requests shall remain available for at least three years from the date that the information was most recently updated.

The IO will consult with the Legal Department concerning responses to requests for such information.