



Research Conflict of Interest and Financial Disclosure Policy

(revised 4/21/2023)

ParaTechs' designated officials to review and address Financial Conflict of Interest (FCOI):

Angelika Fath-Goodin, CEO

Bruce Webb, President

Major Topics

Conflicts of Interest

Disclosure Requirements

Review of Financial Interest Disclosure Statements and Management of Conflicts

Enforcement

I. Policy

Integrity, objectivity, and absence of self-dealing are essential at all levels and in all aspects of ParaTechs activities, including research. ParaTechs and its employees are committed to conducting themselves and their activities in accordance with the highest standards of integrity and ethics. ParaTechs recognizes that actual or potential conflicts of interest may occur in the normal conduct of research and other activities. Thus, it is essential that investigators disclose their and their family members' financial interests related to research for review by ParaTechs. After disclosure ParaTechs can make an informed judgment about a particular activity and require appropriate oversight, limitations, or prohibitions in accordance with this policy.

The Public Health Service of the U.S. Department of Health and Human Services (PHS), has adopted regulations on promoting objectivity in research. These regulations (the "PHS-regulations"), which include in particular 42 C.F.R. Part 50 Subpart F and 45 C.F.R. Part 94, describe the actions an individual and an organization must take in order to promote objectivity in research. The regulations apply to all PHS funded grants, cooperative agreements, research or other contracts (but not Phase I Small Business Innovation Research or Small Business Technology Transfer program grants), and applications or proposals for such grants, agreements and contracts, and subawards where the originating sponsor providing the funding is the PHS or a PHS Awarding Component.

These PHS-regulations require that investigators at the Institution submitting proposals or applications for funding, on behalf of a subrecipient, where the prime sponsor is the PHS, prior to the submission of the subaward application or proposal to the PHS Grantee (as defined below), disclose to Institution any significant financial interests related to their institutional responsibilities at the Institution.

For purposes of this policy a "PHS Grantee" is, as applicable, (i) the Institution or (ii) another entity or

organization, whether a U.S. domestic or a foreign, public or private, entity or organization (but excluding a United States federal agency) that is applying for, or that receives a prime award from the PHS or any PHS Awarding Component (as that term is defined below) or that enters into a contract with PHS or any PHS Awarding Component (and provides property or services under such contract for the direct benefit or use of the United States federal government) or that submits a proposal for such contract, and, under that prime award for PHS-funded Research or contract, the PHS Grantee issues a subaward to the Institution as the subrecipient. References to prime award include, as applicable, the prime award or a contract between PHS or a PHS Awarding Component and the PHS Grantee, and references to subaward include, as applicable the subaward to the Institution as the subrecipient from a PHS Grantee that is not the Institution or the (sub)contract between the Institution as the subcontractor and a PHS Grantee that is not the Institution.

If the Institution carries out any PHS-funded Research through a subrecipient (e.g., subcontractors, or consortium members), the Institution must take reasonable steps to ensure that any subrecipient Investigator incorporates, as part of a written agreement with the subrecipient, terms that establish whether this policy or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's Investigators. If Institution agrees that the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of such agreement that its policy complies with the PHS-regulations. If the subrecipient cannot provide such certification, the agreement must state that subrecipient Investigators are subject to this policy of Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the Institution. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the above-referenced agreement must specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the Institution. Such time period(s) must be sufficient to enable the Institution to comply with this policy to provide timely reports to the PHS or any PHS Awarding Component or PHS Grantee or otherwise required by the PHS-regulations. If this policy applies to any subrecipient Investigators and subrecipient Investigators are subject to this policy of Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the Institution, for purposes of the relationship between Institution and the subrecipient, the PHS Grantee referenced in this policy shall be deemed to be the Institution.

This policy has been developed to comply with the above- referenced specific U.S. federal agency requirements and regulations, which were promulgated to promote objectivity in research by establishing standards that provide a reasonable expectation ensuring the design, conduct and reporting of PHS- funded research, including research funded under National Institutes of Health (NIH) grants or cooperative agreements, will be free from bias resulting from investigator financial conflicts of interest.

This policy governing financial conflict of interest applies to all Investigators (as defined below) at the Institution.

The Institutional Official (as defined below) is responsible for ensuring implementation of this policy on behalf of the Institution.

II. Purpose

In compliance with state and Federal law, this regulation sets forth policies, principles, and procedures to ensure that the personal financial interests of ParaTechs employees do not compromise:

- A. The objectivity with which research is designed, conducted, and reported;
- B. The welfare of research participants; or
- C. The objectivity with which intellectual property is developed.

III. Scope

This regulation applies to all employees involved in research and related activities and to the disclosure and subsequent development of intellectual property.

IV. Definitions

The following definitions apply to this regulation, unless a different definition is used by an applicable federal agency. In that case, the definition used in the federal agency's regulations will apply.

- A. "*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.
- B. "*Institution*" means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives NIH research funding.
- C. "*Entity*" means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.
- D. "*Senior/Key Personnel*" means the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under the regulation.
- E. "*Investigator*" means 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 the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty) the risk is that an unidentified FCOI may compromise the research enterprise increases.
- F. "*Family Member*" means spouse or dependent child.
- G. "*Associated Entity*" means any trust, organization, or enterprise over which an investigator or a family member of the investigator, individually or collectively, exercises a controlling interest.
- H. "*Research*" or "*Research Activity*" means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research such as bench work, clinical trials or other work and product development, and other forms of creative activity. The term includes any such research or creative activity conducted at ParaTechs, or conducted in situations in which ParaTechs positions or titles are utilized in resultant publications, presentations, or

other forms of intellectual property, irrespective of whether such research is funded by contract, gift, cooperative agreement, or general funds of the Commonwealth. The term also includes collaborative work with a manufacturer, a distributor, or a sponsor of the research and includes any tangible or intangible inventions, discoveries, patents, or ideas necessary for development, utilization or processes associated with the activity.

I. "*Institutional responsibilities*" are defined as an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on Financial Conflict of Interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. The Institution can include other professional responsibilities within the definition, as appropriate.

J. A "*Financial Conflict of Interest*" (FCOI) exists when the Institution, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

K. "*Relevant Significant Financial Interest*" means an interest that would reasonably appear to be affected by the research for which funding is sought.

L. "*Significant Financial Interest*" (SFI) means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The 2011 PHS revised regulation defines a "Significant Financial Interest" as follows:

(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 disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. 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. ParaTechs Corp. applies the \$5,000 de minimis threshold to all reimbursed or sponsored travel disclosure.

(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 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 located in the United States, a United States 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 a United States Institution of higher education; or income from service on advisory committees or review panels for a United States federal, state, or local government agency, a United States 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 a United States Institution of higher education. Unlicensed intellectual property that does not generate income is also excluded from the definition of Significant Financial Interest (SFI).

Investigators must disclose all **foreign financial interests** (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

M. “*Institutional Official*” means ParaTechs’ appointed official (CEO; President) who solicits and reviews disclosures of SFI of the Investigator (and those of the Investigator’s spouse and dependent children) related to an Investigator’s institutional responsibilities for a determination of FCOI.

N. “*Retrospective review*” means that whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the Institution shall, within 120 days of the Institution’s determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the NIH-funded research project 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.

VI. Conflicts of Interest

A. A potential or actual conflict of interest exists when a significant financial interest (as defined herein) of an investigator, a family member of the investigator or an associated entity, would reasonably appear to be affected by the research activities of the investigator or the development of intellectual property.

B. An investigator may not engage in research activities in which a potential or actual conflict of interest exists in fact or develop intellectual property for which actual or potential conflict exists, unless authorized in writing by ParaTechs and conducted in full accord with conditions and restrictions imposed by ParaTechs.

VII. Disclosure Requirements

A. No application for funding (except Phase I SBIR/STTR applicants) from an external agency may be submitted to the agency until all investigators have completed required disclosure forms. Disclosure forms must be completed even if no relevant significant financial interest exists.

B. An investigator shall disclose their foreign and domestic relevant significant financial interests (as defined above) of the investigator and the investigator's family members over the previous twelve-month period:

1. At the time an application is submitted for external research support;
2. The initial disclosure of SFIs over the previous twelve-month period provides baseline information that allows Institutions to take into account whether Investigators have an ongoing financial relationship with an entity providing a payment or reimbursement or whether the payment or reimbursement was limited in duration.
3. Once Investigators have made their initial disclosure, they are required to update their disclosures within 30 days of discovering or acquiring a new SFI and annually during the period of award.
4. Prior to submission of intellectual property (e.g., copyrights, patents, and trademarks) for registration or filing.

C. For so long as the research is ongoing, disclosures under this provision relating to ongoing research must be updated either on an annual basis or any time a relevant significant financial interest, not originally disclosed, develops or is acquired. The investigator has to disclose SFI to the designated Institutional Official(s) within 30 days of discovering or acquiring a new SFI. Disclosures under this provision related to intellectual property shall be updated prior to the execution of any contract, license, or other transaction involving the intellectual property.

D. Disclosure requirements also apply to reimbursed or sponsored travel received by the Investigator's spouse and dependent children that is related to the Investigator's institutional responsibilities.

E. Disclosures required by this provision shall be submitted to ParaTechs.

F. Disclosures shall be made on standard disclosure forms available from ParaTechs.

G. ParaTechs is responsible for reporting all identified Financial Conflict of Interests (FCOIs) for subrecipient investigators to the NIH through the eRA Commons FCOI Module. A written agreement states whether the subrecipient will follow ParaTechs' or its own FCOI policy. If applicable, obtain a certification form from the subrecipient that its FCOI policy complies with federal regulations. If the subrecipient's FCOI policy applies to subrecipient Investigators, the subrecipient shall report all identified FCOIs to ParaTechs in a time period sufficient to enable ParaTechs to comply with its review, management and reporting obligations. Alternatively, if no FCOI policy of the subrecipient institution is available, the subrecipient will follow ParaTechs' FCOI policy and Financial Interest Disclosure Statements.

VIII. Review of Financial Interest Disclosure Statements and Management of Conflicts

A. Review of Financial Interest Disclosure Statements

ParaTechs' Institutional Official(s) shall promptly review disclosure statements for the purpose of determining if a relevant significant financial interest related to PHS-funded research is disclosed. If the disclosure statement reveals any relevant significant financial interest, a potential or actual conflict exists.

B. No Relevant Significant Financial Interest Disclosed

If the review reveals no relevant significant financial interest, disclosure statements shall immediately

be forwarded to ParaTechs, and no further action is required.

C. Significant Financial Interest Disclosed and Management of Conflicts

A conflict of interest exists and management of a relevant significant financial interest is required if a person could reasonably conclude that the interest could directly and significantly affect the design, conduct, or reporting of the research activity under consideration, the protection of research participants, or the development of intellectual property. When a relevant significant financial interest is disclosed, the following actions must be completed prior to expenditure of any funds under the award, or prior to the submission of intellectual property for registration:

1. The Institutional Official shall consult with the investigator and the parties shall jointly review the disclosure statement. If a potential or actual conflict of interest is eliminated by agreement of the parties (e.g., through divestiture of interest, severance of relationships), no further action is required except that the Institutional Official shall provide a written confirmation of the agreement of the parties.
2. If elimination of the conflict or potential conflict is not possible, the investigator shall propose a course of action to manage or reduce the conflict. The Institutional Official may offer assistance with the plan. In any case, the Institutional Official shall review the plan proposed by the investigator and may attach additional comments or information. For research involving human subjects the plan shall be designed so that the financial interest does not affect the risk to or welfare of research participants. A report needs to be filed with DHHS through the eRA commons.

Examples of conditions or restrictions that may be employed to manage, reduce, or eliminate such conflicts include:

- i. Public disclosure of significant financial interests (e.g. public presentation of the results of the research; addendum to previously published presentations);
- ii. Monitoring of the research by independent reviewers;
- iii. Modification of the research plan;
- iv. Change of personnel or personnel responsibilities
- v. Disqualification from participation in all or a portion of the research;
- vi. Reduction or elimination of the significant financial interest (e.g., sale of an equity interest); or
- vii. Severance of relationships that create the actual or potential conflict of interest.

A management plan needs to be implemented within sixty days whenever an Institution identifies an SFI that was not disclosed timely by an Investigator. The Investigator's compliance with the management plan needs to be monitored until completion of the project.

3. ParaTechs is required to conduct a retrospective review in those cases of non-compliance with the regulations. ParaTechs will be required to notify the PHS Awarding Component promptly and submit a Mitigation Report to the PHS Awarding Component in cases where bias is found. The report will address the impact of the bias on the research project and the actions ParaTechs has taken, or will take, to eliminate or mitigate the effect of the bias. Retrospective reviews shall be completed and documented consistent with the regulation within 120 days of determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner.

D. Conflict of Interest Management Reports to the NIH

The plan recommended by the Institutional Official may require a FCOI report to the NIH through the eRA commons FCOI module. A report shall be filed prior to the expenditure of funds if a FCOI was determined before the start-date of the PHS funded project; within sixty days of identification of a FCOI for an Investigator who is newly participating in the project; within sixty days for new, or newly identified, FCOIs for existing investigators. A report shall be filed annually to provide the status of the FCOI and any changes to the management plan and at the end of the project. If appropriate, a FCOI report shall be submitted to update a previously submitted report following a retrospective review. Reports shall document the actions taken to implement the conditions outlined in the plan.

IX. Reporting Requirement

A. Initial Reports

Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution must provide to the NIH an FCOI report regarding any Investigator Significant Financial Interest (SFI) found by the Institution to be a FCOI in accordance with the regulation. The Institution must also provide an FCOI report whenever an Investigator does not timely disclose a SFI or whenever the Institution, for whatever reason, does not review a disclosed SFI and the Institution then determines that a FCOI exists.

The FCOI report to the NIH must include the following key elements:

- i. Project number;
- ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- iii. Name of the Investigator with the Financial Conflict of Interest;
- iv. Name of the entity with which the Investigator has a Financial Conflict of Interest;
- v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- vi. 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;
- vii. A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research;
- viii. A description of the key elements of the Institution's management plan, including:
 - (A) Role and principal duties of the conflicted Investigator in the research project;
 - (B) Conditions of the management plan
 - (C) How the management plan is designed to safeguard objectivity in the research project;
 - (D) Confirmation of the Investigator's agreement to the management plan;
 - (E) How the management plan will be monitored to ensure Investigator compliance; and
 - (F) Other information as needed.

B. Submission of Initial FCOI reports during an Ongoing NIH-funded Research Project:

1. The Institution must submit an FCOI report within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new SFI to the Institution during the period of award.
2. Whenever an Investigator does not disclose timely a previously existing SFI or fails to comply with a FCOI management plan, or the Institution fails to review or manage a previously existing SFI during an ongoing NIH-funded project, the Institution's designated official(s) shall, within sixty (60) days: review the SFI; determine whether it is related to the NIH-funded research; determine whether a FCOI exists. If so, the Institution must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI going forward and submit an FCOI report to the NIH.

C. Retrospective Review

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

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
- Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project 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.

The Institution shall document the retrospective review which must include at least the following key elements:

- A. Project number;
- B. Project title;
- C. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- D. Name of the Investigator with the FCOI;
- E. Name of the entity with which the Investigator has a financial conflict of interest
- F. Reason(s) for the retrospective review;
- G. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- H. Findings of the review; and
- I. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, the Institution must notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report is submitted as a "Revised FCOI Report." (see FAQ H.2. <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52885>). 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 the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

D. Annual FCOI Report:

For any FCOI previously reported by the Institution, the Institution shall provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports must be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when the Institution is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of a project extension with or without funds (see FAQ H.35).

The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module. In addition, please note that the annual FCOI report is not to be submitted as part of the annual progress report nor is it a grant closeout requirement.

E. Public Accessibility:

Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible web-site or written response within five business days of a request, of information concerning any SFI disclosed to the Institution that meets the following three criteria:

- A. The SFI was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- B. The Institution determines that the SFI is related to the NIH-funded research; and

C. The Institution determines that the SFI is a **Financial Conflict of Interest**.

The information that the Institution makes available via a publicly accessible web-site or written response shall include, at a minimum, the following:

- i. Investigator's name;
- ii. Investigator's title and role with respect to the research project;
- iii. Name of the entity in which the Significant Financial Interest is held;
- iv. Nature of the Significant Financial Interest; and
- v. Approximate dollar value of the Significant 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.
- vi. Contact information

The information on the publicly accessible web-site shall be updated at least annually. In addition, the Institution shall update the Web site within sixty (60) days of the Institution's receipt or identification of information concerning any additional SFI of the senior/key personnel for the NIH-funded research project that was not previously disclosed, or upon the disclosure of a SFI of senior/key personnel; or upon the disclosure of a SFI of senior/key personnel new to the NIH-funded research. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new FCOI. The publicly accessible information will remain available for three (3) years from the date the information was most recently updated. If the Institution responds to written requests, the Institution 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 the Institution's identification of a new FCOI, which should be requested subsequently by the requestor.

X. Enforcement

A. NIH shall be notified promptly if an Investigator fails to comply with ParaTechs' FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

B. The following acts and failures violate the provisions of this regulation:

1. Intentionally or recklessly providing incomplete, erroneous, or misleading information on a disclosure form;
2. Failing for any reason to make any required disclosure;
3. Failing to provide requested information needed for an appropriate review of potential or actual conflict of interest situations.

C. A violation of this regulation is grounds for the discipline of an investigator or other employee. Sanctions that may be imposed for such a violation include but are not limited to any one or more of the following:

1. Involuntary termination of employment;
2. Non-renewal of appointment;
3. Suspension;
4. Letter of admonition;

5. Public disaffirmation of the research;
6. Notification to regulatory bodies (e.g., U.S. Patent Office, Copyright Office);
7. Notification to actual or potential research funding agencies; and
8. Protest to editorial boards.

D. Disciplinary proceedings initiated under this regulation shall be conducted in accordance with the Governing and Administrative Regulations the Human Resources Policy and Procedures.

XI. Training

Each Investigator (as defined above), including subrecipient Investigator(s), must complete training prior to engaging in NIH-funded research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.

To satisfy the NIH FCOI training requirements ParaTechs is utilizing resources available on NIH's Office of Extramural Research Financial Conflict of Interest Web page found at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

The responsibility of the Institution is to inform each investigator of the

- Institution's policy
- Investigator's disclosure responsibilities of all foreign and domestic significant financial interest
- Federal regulations (<http://grants.nih.gov/grants/policy/coi/>)
- Require each PHS-supported Investigator to complete FCOI training as outlined above

XII. Miscellaneous

A. Disclosure statements, other documentation used in the review of such statements, and records of institutional action taken pursuant to this policy shall be maintained at ParaTechs for a period of three (3) years following completion of the research project that generated the disclosure statements, documentation, or institutional actions, for a period of time needed for resolution of government action involving such records. To the extent permitted by law, such records shall be maintained confidentially.

B. ParaTechs shall make the information described in the preceding paragraph available as prescribed by the sponsoring agency's policy or, upon request, to external funding agencies, along with requested information as to how a relevant potential or actual conflict of interest was managed, reduced, or eliminated to protect the objectivity of the research. If a potential or actual conflict of interest is identified after a grant or contract has been awarded, ParaTechs shall inform the awarding agency of that conflict within sixty (60) days of its discovery (or as otherwise required by law) along with actions taken to manage, reduce, or eliminate the actual or potential conflict of interest.

C. If ParaTechs ever determines that it is unable to manage satisfactorily a potential or actual conflict of interest that threatens the objectivity of particular research activity; ParaTechs shall promptly inform the relevant external funding agencies of that fact as required by the agency policy.

D. In making applications for external funding of research activities, investigators will be required to certify that they have read and understood ParaTechs' FCOI policy, the federal regulations and their responsibility to disclose any financial interest. FCOI training for each investigator is required prior to engaging in research related to any PHS-funded grant; at least every four years; immediately if ParaTechs revises its FCOI policy that affects requirements of investigators, an investigator is new to the institution and an investigator is not in compliance with the policy or management plan. (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)

E. ParaTechs shall make the information described herein publicly accessible through their web-site. ParaTechs shall make available information concerning identified FCOIs held by senior/key personnel publicly accessible prior to the expenditure of funds. This information shall be up-dated at least annually or within sixty days of a newly identified FCOI.

F. ParaTechs is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. Awardee institutions must incorporate as part of a written agreement with a subrecipient terms that establish whether ParaTechs' FCOI policy or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient Institutions who rely on their FCOI policy must provide a certificate stating that its FCOI policy complies with the regulation and report identified financial conflicts of interests to ParaTechs in sufficient time to allow ParaTechs to report the FCOI to the NIH to meet its reporting obligations. Subrecipient institutions that must comply with the awardee Institution's policy must submit all Investigator disclosures of SFI to the awardee in sufficient time to allow the awardee to review, manage and report identified FCOIs to the NIH. Awardee Institutions are responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOI to the NIH.

XIII. References and Related Materials

National Institutes of Health 42 CFR Part 50 Subpart F
National Science Foundation "Award and Administrative Guide" Chapter IV.A
Association for the Accreditation of Human Research Protection Programs (AAHRPP)
2018 FCOI tutorial https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Amendment 1:

Major changes to the 1995 regulations:

Significant Financial Interests (SFI) threshold	De minimis threshold of \$5,000 for disclosure generally applies to payments for services and/or equity interests. Includes any equity interest in non-publicly traded entities.
Which SFIs need to be disclosed (once the threshold is met)	All SFI related to the Investigator's institutional responsibilities.
Excluded from disclosure requirement	Income from seminars, lectures, or teaching engagements sponsored by and service on advisory 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. These exclusions do not apply to foreign financial interest.
Types of SFI excluded	Excludes 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.
Travel reimbursements and sponsored travel	Disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). NOT required to disclose 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 will determine if any travel requires further investigation, including determination or disclosure of the monetary value.

<p>Information on an identified Financial Conflict of Interest (FCOI) reported by the Institution to the PHS Awarding Component</p>	<p>INITIAL REPORT Requirements in 1995 regulations, plus: Name of the entity with which the Investigator has a FCOI Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-\$100K by increments of \$20K; amts above \$100K by increments of \$50K or statement that a value cannot be readily determined. A description how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research Key elements of the Institution's management plan ANNUAL REPORT status of the FCOI changes to the management plan.</p>
<p>Subrecipient Institutions/Investigators and Reporting of identified FCOIs</p>	<p>Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS Awarding Component (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations.</p>
<p>Public Accessibility</p>	<p>Make information available concerning identified FCOIs held by senior/key personnel via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the rule. This information will include at a minimum 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.</p>
<p>FCOI training</p>	<p>Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the designated circumstances: institutional FCOI policies change in a manner that affects Investigator requirements an Investigator is new to an Institution an Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.</p>

Retrospective Review (“Mitigation plan,” discussed in NPRM)	Institution is required to conduct a retrospective review in those cases of non-compliance with the regulations. The Institution will be required to notify the PHS Awarding Component promptly and submit a report to the PHS Awarding Component in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.
---	--



Research Financial Interest Disclosure Statement

This form must be completed by all “investigators,” defined as the principal investigator, co investigators, and any other employee who is responsible for the design, conduct or reporting of project activities. The form must be submitted to the CEO at the time an application is submitted for external research support; 2) prior to submission of intellectual property for registration or filing.

Name:
Title & Position:
Email:
Principal Investigator:
Proposal Title:
Proposal Deadline:
Sponsor:

This Research Financial Interest Disclosure Statement is to be completed in compliance with ParaTechs’ “Research Conflict of Interest and Financial Disclosure Policy”. Please refer to the regulations for definitions of the terms used herein. Please note, answering “yes” to any of the following questions does not mean the financial interest is inappropriate or improper, it means only that disclosure and evaluation, and in some cases, approval and oversight, are required. For further information, refer to the policy document.

All thresholds listed below are an aggregate for the investigator, his or her spouse, and dependent children. “You” refers to the investigator, spouse and dependent children.

1. Financial Compensation from or Management Responsibilities in Related Businesses

YES NO

Are you (and spouse and dependent children) currently receiving income from a business in any way related to or that might be affected by your proposed research activities or transfer of technology, and that when aggregated at the time of disclosure (over the 12 months preceding the disclosure) and/or over the next twelve months is expected to exceed \$5,000?

Examples of income include consulting, speaker’s, or other fees, honoraria, gift funds, stocks or stock options as payments, salary, allowance, dividend, rent, capital gain, real or personal property.

Please list the name of the entity/entities where the financial conflict of interest (FCI) exists, and the value of the FCI. Please specify if the FCI is from a publicly traded or non-publicly traded entity.

2. Equity Interest in Related Businesses

YES NO

Are you (and spouse and dependent children) currently holding financial interests exceeding \$5,000 or equity interest (e.g., stock, stock option, or other ownership interest) in a business enterprise related to your proposed research activities or transfer of technology?

Please list the name of the entity/entities where the financial conflict of interest exists, and the value of the financial conflict of interest.

3. Intellectual Property and Related Businesses

YES NO

Are you (and spouse and dependent children) currently entitled to receive compensation from a business enterprise due to intellectual property (e.g. patents, copyrights, or royalty agreements) in any way related to or that might be affected by your proposed research or transfer of technology?

4. Reimbursed or Sponsored Travel

YES NO

Have you (and spouse and dependent children) been reimbursed or conducted sponsored travel? If “yes”, please provide at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Additional information may need to be provided upon request.

5. Financial interest received from a foreign entity?

YES NO

Disclosure is required for all financial interests received from a foreign institution of higher education or the government of another country when such income exceeds \$5,000.

6. Other Relevant Financial Interest?

YES NO

Are there any other situations not covered above that might possibly be affected by the research?

If you have answered “yes” to any of the above questions, attach a description of the safeguards you will put in place to protect the welfare of research subjects and ensure that the financial interest does not impact research participants.

Please note that you may be asked for more specific information.

I have read and understood ParaTechs’ “Research Conflict of Interest Financial Disclosure Policy”; have made all required financial interest disclosures; will submit a proposal for a Conflict of Interest Management Plan if necessary; and will comply with any conditions or restrictions imposed by ParaTechs to manage, reduce, or eliminate conflicts of interest regarding my research.

Signature

Date

Place completed disclosure form and forward to ParaTechs’ CEO or President.

TO BE COMPLETED BY PARATECHS' CEO or President

Were any potential conflicts noted? **YES** **NO**

If **YES**, refer to the policy document. The investigator must propose a management plan to eliminate, reduce or manage the conflict and you may provide assistance.

Printed Name

Signature **Date**