Research Conflict of Interest and Financial Disclosure Policy

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.

II. Purpose

In compliance with state and Federal law, this regulation sets forth policies, principles, and procedures to ensure that the personal financial interests 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. "Investigator" means the principal investigator, a co-principal investigator, and any other person at ParaTechs who is responsible for the design, conduct, or reporting of research.

B. "Family Member" means spouse or dependent child.

C. "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.

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

E. "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.

F. "Significant Financial Interest" (FCI) 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). For research involving human subjects, “significant financial interest” also includes employee or executive relationships with entities that have a financial interest in the research even when no remuneration is involved or financial interest in the sponsor, product, or service being tested. The term does not include any of the following:

1. Salary or other remuneration from ParaTechs;
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. Income (e.g., salary, fees, or other continuing payments) in an amount of $5,000 or less per annum from any one business enterprise or entity when aggregated for the investigator and members of the investigator’s family; and
5. Financial interests in any one business enterprise or entity if the value of those interests does not exceed $5,000 in value as determined through public prices or other reasonable measures of fair market value, and does not represent more than a five percent (5%) ownership interest when aggregated for the investigator and members of the investigator’s family.

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 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 relevant significant financial interests of the investigator and the investigator’s family members:

1. At the time an application is submitted for external research support;
2. 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. Disclosures required by this provision shall be submitted to ParaTechs.

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

F. 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 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 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 CEO 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 CEO 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 CEO may offer assistance with the plan. In any case, the CEO 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. Disqualification from participation in all or a portion of the research;
v. Divestiture of the significant financial interest; or
vi. 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 CEO may require a FCOI report to the NIH through the eRA commons. A report shall be filled 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. 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. 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.

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.

C-06 1/12 revised 9/12
XI. 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)
Amendment 1:
Major changes to the 1995 regulations:

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<tr>
<th>Significant Financial Interests (SFI) threshold</th>
<th>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.</th>
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<tr>
<td>Which SFIs need to be disclosed (once the threshold is met)</td>
<td>All SFI related to the Investigator’s institutional responsibilities.</td>
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<tr>
<td>Excluded from disclosure requirement</td>
<td>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.</td>
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<td>Types of SFI excluded</td>
<td>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.</td>
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<td>Travel reimbursements and sponsored travel</td>
<td>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.</td>
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<td>Information on an identified Financial Conflict of Interest (FCOI) reported by the Institution to the PHS Awarding Component</td>
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| **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

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<th>Subrecipient Institutions/Investigators and Reporting of identified FCOIs</th>
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| 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.

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<th>Public Accessibility</th>
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| 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.

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<th>FCOI training</th>
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| 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. |
| **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.** |