

3P BIOTECHNOLOGIES' FINANCIAL CONFLICTS OF INTEREST POLICY FOR FEDERALLY-FUNDED RESEARCH

The federal government requires that organizations establish and administer a financial conflict of interest (FCOI) and disclosure policy for investigators who conduct research funded by federal grants. This standard is designed to ensure appropriate management of actual or potential conflicts of interest. As such, 3P Biotechnologies has developed the following policy that fulfills the requirements of grantee institutions as put forth in the National Institutes of Health's guidelines (<https://grants.nih.gov/grants/policy/coi/index.htm>) and the National Science Foundation's conflict of interest policy (https://www.nsf.gov/pubs/policydocs/pappg18_1/pappg_9.jsp).

A. FINANCIAL CONFLICTS OF INTEREST IN RESEARCH POLICY

A-1. Purpose. To promote objectivity in research and to foster compliance with federal regulations 3P Biotechnologies requires investigators seeking research funding (including but not limited to grants, cooperative agreements, and contracts) or having obtained research funding from the Public Health Service (PHS), the National Science Foundation (NSF), or other federal agencies to comply with the following policy on the disclosure of significant financial interests (SFIs) and the management and reporting of financial conflicts of interest. Section B of this policy is intended to comply with the PHS regulations on *Promoting Objectivity in Research* (42 C.F.R. 50 and 45 C.F.R. 94), and Section C of this policy specifically governs research funded by the NSF.

A-2. Responsible Authority: Chief Operating Officer. The Chief Operating Officer (COO), or his or her designee(s), shall be the authority who provides and monitors training of investigators required by federal regulations and/or policy; evaluates all disclosures by investigators made under this policy; determines whether a financial conflict of interest exists; develops and implements a management plan for financial conflicts of interest subject to this policy; performs retrospective review of potential instances of noncompliance with this policy; makes, as required by federal regulation, information on investigator financial conflicts of interest publicly available; and reports, as required by federal regulation, on the company's determination of the existence of a financial conflict of interest, implementation of management plan for a financial conflict of interest, determination of noncompliance, and the results of any retrospective review.

Circumstances for designation of responsibility include, but are not limited to, obtaining a second opinion on potential conflicts of interest or during retrospective reviews, development of appropriate management plans, training of investigators, as described below, or reporting, as required by federal regulation.

A-3. Disclosure of significant financial interests. All personnel responsible for the design, conduct or reporting of research under the terms of a federal grant, cooperative agreement or contract (each, an "Investigator") are required to disclose to the COO all Significant Financial Interests of the Investigator and/or the Investigator's spouse and dependent children.

The terms of such disclosure, in both the timing and the standards for defining Significant Financial Interest, vary with the source of funding, as described below. When, because of existing funding and/or proposed research, an individual investigator is subject to both the PHS and NSF FCOI requirements, the PHS requirements set forth in Section B shall prevail.

A-4. Subawardees and subcontracts. When 3P Biotechnologies is a subawardee or subcontractor of another institution, the 3P policy will apply, unless the terms of the subaward or subcontract expressly prohibit it. Conversely, 3P Biotechnologies requires its subcontractors and subawardees to develop and manage their own federally compliant conflict of interest policies as appropriate to each funding agency.

B. POLICY APPLICABLE TO PHS FUNDING

Public Health Service (PHS) regulations provide a broad definition for “investigator” but strict *de minimis* standards for reporting, public accessibility requirements, management responsibilities, and the requirements for training in conflict of interest. The standards in Section B apply to PHS-funded research; different standards apply to NSF-funded work, as described in Section C. The language of the published PHS regulations is included by reference (42 C.F.R. Part 50, Subpart F).

B-1. Definitions for PHS-funded Research.

Investigator refers to the project director, principal investigator, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS). In addition to 3P investigators, this definition may apply to staff, consultants, or others with independent responsibility for portions of the design, conduct, or reporting of research of an Investigator’s proposed or funded project, or when they seek research funding subject to this policy.

Each project director or principal investigator is responsible for determining all project personnel who meet the above definition of Investigator and therefore who must be trained, must disclose financial interests to 3P, and must report when the status of any financial interest changes or when new interests are acquired. In making such determinations, the project director/PI should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

Significant Financial Interest (SFI-PHS) means one or more of the following interests of the Investigator (or the Investigator’s spouse or dependent children), if it reasonably appears to be related to the Investigator’s institutional responsibilities, including all research and/or service to 3P:

a) With regard to any *publicly traded entity*, an SFI-PHS 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 the disclosure, when aggregated, exceeds \$5,000. Remuneration includes any salary and any payment for services not otherwise identified as salary (e.g., consulting fees, paid authorship, honoraria); 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.

b) With regard to any *non-publicly traded entity*, an SFI-PHS 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) owns *any* equity interest, regardless of dollar value.

c) With regard to *intellectual property rights and interests* (e.g., patents and copyrights) an SFI-PHS exists upon receipt of income related to such rights and interests.

d) Any occurrence of *sponsored travel* (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) or any reimbursed travel related to the Investigator's institutional responsibilities must also be disclosed, with the exception of any travel 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 Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be required.

e) *Exclusions*. An SFI-PHS does not include the following types of financial interests:

- salary, royalties, or other remuneration from 3P Biotechnologies;
- income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Financial Conflict of Interest exists when a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally-funded research or educational activities.

B-2. Disclosure for PHS-funded Research.

Investigators must disclose all SFI-PHS (as defined above) at or before the time a proposal is submitted to any component of the PHS. In addition, Investigators must update those financial disclosures:

- Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest; and

- Annually within the period of the award, beginning with the anniversary date of the original disclosure.

B-3. Training for PHS-funded Research.

Training requirements apply to any PHS-funded research as follows.

- *Active NIH/PHS-funded projects.* Each Investigator on projects funded by NIH or other PHS-affiliated agencies must complete training in financial conflict of interest policy. Training consists of a mandatory review of the 3P policy and completion of the NIH COI tutorial (https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html). All Investigators must complete such training prior to applying for PHS funding or the renewal date of the existing award, whichever occurs first.
- *New or previously unfunded projects.* New and/or previously unfunded Investigators who submit a research proposal are required to complete training (and make the disclosures described above) prior to submission of their proposal to NIH or another PHS-affiliated agency.
- *Re-training.* Training of active NIH/PHS-funded Investigators will be repeated (i) every four years, or when 3P finds that an Investigator is not in compliance with this policy, and (ii) on any occasion when 3P revises its Financial Conflict of Interest policies and procedures in any manner that affects the requirements of Investigators. When such revisions occur, re-training must occur within 45 days of the issue date of the revised policy.

B-4. Review of Financial Disclosures (PHS funding).

Determination of Financial Conflicts of Interest. The COO (or his or her designee) shall review each disclosed SFI; determine whether such SFI relates to federally-funded research, and, if so related, determine whether a Financial Conflict of Interest (FCOI, as defined above) exists; and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict of interest. The COO may, depending on the scope of the potential conflict, request that additional staff or appropriate consultants serve on an *ad hoc* review committee to assist in this review, and they or the COO may request additional information from the Investigator who disclosed the SFI. No individual may participate in the review of his or her own SFI Disclosure.

Management of Financial Conflicts of Interest. If the COO and/or the review committee determines that a Significant Financial Interest constitutes a Financial Conflict of Interest, the COO/review committee shall determine the conditions or restrictions to be imposed and implemented as part of a formal management plan in order to manage or eliminate the conflict. The Management Plan may include, but is not limited to, these elements:

- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in the portion of the federally-funded research that would be affected by Significant Financial Interests;
- divestiture of Significant Financial Interests;
- severance of relationships that create conflicts; or,
- public disclosure of Financial Conflicts of Interest.

The COO shall communicate this determination and the means that he or she has identified for eliminating or managing the FCOI to the individual Investigator, the relevant Principal Investigator or Project Director (if applicable), the President, and, as necessary, the PHS awarding component.

No expenditures on PHS awards will be permitted until the Investigator has complied with the disclosure and training requirements of this policy and has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of the FCOI.

B-5. Reporting Financial Conflicts of Interest (PHS funding).

a) *Sponsoring agency.* Significant Financial Interests that are determined to be Financial Conflicts of Interest will be reported to the PHS sponsoring agency within 60 days of the original disclosure.

b) *Public request.* Information on Financial Conflicts of Interest will be made available to members of the public in response to inquiries within 5 business days of receipt of such requests.

C. POLICY APPLICABLE TO NSF FUNDING

In contrast to the PHS regulations described above, regulations regarding conflict of interest for NSF-funded research are less restrictive. Accordingly, the *de minimis* standard for reporting is \$10,000, the definition of reportable financial interests is less stringent, no training is mandated, and the reporting requirements are less onerous. These differences are reflected in the policy below that pertains to NSF-funded research or educational activities.

C-1. Definitions for NSF-funded Research.

Investigator means the principal investigator/project director, co-principal investigators/co-project directors, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

Significant financial interest (SFI-NSF) means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

- salary, royalties or other remuneration from the applicant institution;
- any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- income from service on advisory committees or review panels for public or nonprofit entities;
- an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: (i) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and (ii) does not represent more than a 5% ownership interest in any single entity; or

- salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve-month period.

C-2. Disclosure for NSF-funded Research.

Investigators must have provided all required financial disclosures at the time the proposal is submitted to NSF. Any financial disclosures must be updated during the period of the award, at least on an annual basis, or as new reportable significant financial interests are obtained.

C-3. Review of Financial Disclosures (NSF funding).

The COO (or his or her designee) shall review each financial disclosure, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include, but are not limited to:

- public disclosure of significant financial interests;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;
- divestiture of significant financial interests; or
- severance of relationships that create conflicts.

If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

D. OTHER FUNDING SOURCES

Research by any Investigator (person responsible for the design, conduct, or reporting of research or educational activities) funded or proposed for funding by a federal agency other than NSF or the PHS shall comply with that agency's policies regarding financial conflict of interest.

E. ENFORCEMENT

3P shall establish appropriate procedures and mechanisms for enforcement of this policy. Conditions that may lead to sanctions include but are not limited to failure to fully and timely disclose all

significant financial interests, or required updates to such disclosures; submission of an incomplete, erroneous, or misleading disclosure; or failure to comply with the conditions of a management or mitigation plan.

Sanctions may include, but are not limited to, any one or more of the following:

- letter of admonition;
- temporary suspension of access to active research funding, either for a fixed term or pending completion of a remediation plan;
- temporary suspension of rights to apply for internal and external research funding as a PI, either for a fixed term or pending completion of re-training and remediation;
- investigation and mitigation of possible research bias resulting from improperly disclosed Significant Financial Interests, and reporting of corrective action to the relevant funding agency/agencies;
- inquiry into possible research misconduct in accordance with 3P's policies and procedures; and,
- disciplinary measures up to and including non-renewal of employment or involuntary termination.

All relevant regulatory bodies and funding agencies will be promptly informed of disciplinary sanctions.

In the case of PHS-funded research, 3P will conduct a retrospective review of any failure to comply within 120 days of determination of noncompliance, as required by federal regulations. In the case of NSF-funded research, the COO must also keep NSF's Office of the General Counsel appropriately informed if the company finds that it is unable to satisfactorily manage a conflict of interest. The funding agency may impose sanctions even if 3P chooses not to do so, and sanctions by 3P do not preclude additional sanctions imposed by the funding agency.

F. RECORDS

3P shall maintain records of all financial disclosures and of all actions taken to resolve Financial Conflicts of Interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records, whichever occurs later.

G. DISCLOSURE STATEMENTS

All personnel who are submitting proposals to a federal funder must complete a SFI disclosure form made available by the COO to solicit and review SFIs that reasonably appear related to his/her institutional responsibilities for financial conflicts of interest. By submitting this form, the applicant certifies that he/she has read and understood 3P Biotechnologies' Policy on Financial Conflicts of Interest for Federally-funded Research and that he/she either a) does not have potential FCOIs as defined therein or b) does have potential conflicts (*"I have the following relationships, affiliations, activities, or interests (financial or otherwise) which constitute potential conflicts under 3P's Conflict of*

Interest policy”). In either case, the applicant also declares that he/she will notify the COO of any change or discovery requiring modification of the above statement and will comply with any conditions or restrictions imposed by 3P to manage, reduce or eliminate financial conflicts of interest.

For more information about this policy, please email Wendy Spencer, at wendyspencer3p@gmail.com.