



FINANCIAL CONFLICT OF INTEREST POLICY

A. General

1. General Principals

PAI Life Sciences, Inc. ("PAI Life") receives federal grants, contracts and/or cooperative agreements for research. The Public Health Service (PHS) and Office of Secretary of Health and Human Service (HHS) have published a financial conflict of interest regulation establishing standards and procedures to be followed by institutions that apply for research funding from PHS granting agencies, including the National Institutes of Health (NIH). This regulation is aimed at ensuring that the design, conduct, or reporting of research funded under grants and cooperative agreements will not be biased by any conflicting financial interest of the investigators responsible for the research.

PAI Life, which is covered under the regulation, promotes objectivity in research by establishing this Financial Conflict of Interest Policy to ensure there is no reasonable expectation that the design, conduct, or reporting of federally funded research will be biased by any conflicting financial interest of an Investigator.

2. Financial Conflict of Interest Generally

Generally, a conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to PAI Life such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal financial gain, including use of resources, disclosure of inventions, objectivity in research, certification of compliance of policies, and outside activities.

The NIH defines the existence of a financial conflict of interest when the institution's designated official reasonably determines that a Significant Financial Interest (as defined below) conflict could directly or significantly affect the design, conduct, or reporting of federally funded research. These situations require disclosure and review and approval by PAI Life management.

An example of a financial conflict of interest that should be disclosed to PAI Life is your participation in research that is funded by an entity in which you (or a member of your immediate family, including spouse, dependent children or domestic partner) hold a financial interest.

PAI Life recognizes that financial conflicts of interest are common and often unavoidable. PAI Life employees should conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, the purposes of this policy are to educate PAI Life employees about situations that generate financial conflicts of interest and to provide means to monitor and assess financial conflicts of interest if they arise. All key PAI Life employees and PAI Life principal investigators have an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of commitment or interest arises, employees are urged to discuss the situation with Darrick Carter or an outside legal representative.

3. Definitions

1. "Federal Funding" or "Federal Funds" means funding received for research grants or cooperative agreements from the Public Health Service (PHS), an operating division of the HHS, and any components of the PHS to which the authority involved may be delegated.
2. "Investigator" means the principal investigator and any other person who is responsible for the design, conduct or reporting of research from Federal Funding. Investigator includes the Investigator's spouse and dependent children.
3. "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development and includes any such activity for which Federal Funding is available through a grant or cooperative agreement.
4. "Significant Financial Interest" 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 term does not include:
 - a. Salary, royalties, equity interest, including stock, stock options and other equity interest or other remuneration from PAI Life;
 - b. Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities;
 - c. Income from service on advisory committees or review panels for public or nonprofit entities;
 - d. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: 1) Does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and 2) does not represent more than a five percent (5%) ownership interest in any single entity; or
 - e. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve (12) months are not expected to exceed \$5,000.

B. Responsibilities

1. Investigator

By the time an application is submitted to the PHS for Federal Funding, each Investigator who is planning to participate in the Federally Funded research must submit to Darrick Carter (PAI Life's "Designated Official") a listing of his/her known financial conflicts (and those of his/her spouse and dependent children):

1. Any financial conflict of interest, that has the potential to compromise or bias the professional judgment or objectivity of the Investigator; or



2. Any financial conflict of interest that has the appearance of having the potential to compromise or bias the professional judgment or objectivity of the Investigator.

The Investigator shall update all financial disclosures during the period of the award, either on an annual basis or as new conflicts of interest emerge.

To report the existence or absence of potential financial conflicts of interest, Investigators shall use PAI Life's "Significant Financial Interest Disclosure Form." Please note that this form must be completed even if you have nothing to report.

2. Designated Official & Managing Conflicts of Interest

As PAI Life's Designated Official, Darrick Carter shall review all disclosures and determine whether a financial conflict of interest exists. If one exists, the Designated Official shall determine what actions should be taken by PAI Life to manage, reduce, or eliminate such conflict of interest.

A financial conflict of interest exists when the Designated Official reasonably determines that a Significant Financial Interest could directly or significantly affect the design, conduct, or reporting of the Federally Funded research.

PAI Life's Designated Official shall report the financial conflict of interest to a committee composed of the following individuals: the Designated Official, legal counsel, and other appropriate PAI Life staff members as designated by the Designated Official. The committee shall discuss the financial conflict of interest and shall determine how to manage the conflict.

Examples of conditions or restrictions that the committee might impose to manage financial conflicts of interest include, but are not limited to:

- public disclosure of Significant Financial Interest;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in all or a portion of the Federally Funded research;
- divestiture of Significant Financial Interest(s); or
- severance of relationships that create actual or potential conflicts.

3. PAI Life Sciences, Inc.

PAI Life shall maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR 50 Subpart F and 45 CFR 94 and inform each Investigator of this policy and the Investigator's reporting responsibilities. If Federally Funded research is carried out through subgrantees, contractors, or collaborators, PAI Life shall take reasonable steps to ensure that Investigators working for such entities comply with this Policy, either by requiring those Investigators to comply with this Policy or by requiring the entities to provide assurances to PAI Life that will enable PAI Life to comply with this Policy.



Prior to PAI Life's expenditure of any Federal Funds, PAI Life will report to the Federal Funding agency the existence of a conflicting interest (but not the nature of the interest or other details) found by the Designated Official and assure that the interest has been managed, reduced, or eliminated in accordance with this policy. For any interest that has been identified as conflicting subsequent to PAI Life's initial report under the federal award, the report will be made and the conflicting interest managed, reduced or eliminated, at least on an interim basis, within sixty (60) days of that identification.

Upon request of PHS, PAI Life agrees to make information available regarding all conflicting interests identified by PAI Life and how those interests have been managed, reduced, or eliminated to protect the research from bias.

PAI Life shall maintain records of all financial disclosures and all actions taken by PAI Life with respect to each conflicting interest for at least three (3) years from the date of submission of the final expenditures report to PHS.