



Investigator Financial Conflicts of Interest Policy

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I. Introduction

Effective interactions between research institutions, government, the private sector, and industry are essential to bring about the rapid application of scientific discoveries to address the needs of the nation and to maintain the efficient translation of research findings. However, the resulting relationships, now encouraged in many forms, are increasingly complex, and may involve financial interests that give rise to a Financial Conflict of Interest (FCOI) through its potential to directly and significantly impact the design, conduct or reporting of an Investigator's research in return for a financial benefit to the Investigator or his/her immediate family.

PowerTech Water is committed to avoiding FCOIs that may compromise, or appear to compromise, the integrity and objectivity of research. The keystone of an effective program for identifying and dealing with FCOIs is full disclosure of those financial interests that reasonably appear related to one's institutional responsibilities. This policy provides guidance and procedures for disclosure by Investigators of Significant Financial Interests. After disclosure, PowerTech Water can make an informed judgment about a particular activity and require appropriate oversight, limitations, or prohibitions in accordance with this policy.

This policy deals with financial conflicts of interest of individual Investigators (defined below). Federal regulations governing financial conflicts of interest for Public Health Service-funded activities are promulgated at 42 CFR Part 50 Subpart F (grants) and 45 CFR Part 94 (contracts).

II. Purpose

Pursuant to state statutes and Federal regulations, this policy sets forth policies and procedures to ensure that the personal financial interests of an Investigator do not compromise the objectivity with which research is designed, conducted, and reported.

III. Persons Affected

This policy shall apply to Investigators on any sponsored agreement that is in preparation, has been submitted to a sponsor, or is currently funded, and to Investigators involved in institutionally-sponsored research.

IV. Definitions

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

A. Equity Interest

Equity interest means stock, stock options, warrants, partnership or other ownership interests. Excluded from this definition are equity interests held in publicly-traded mutual funds or retirement programs the investment of which is not under the control of the Investigator or family member, including PowerTech Water retirement programs.

B. Family Member

Family member means an Investigator's spouse and dependent children.

C. Financial Conflict of Interest

Financial Conflict of Interest or FCOI means a [Significant Financial Interest](#) that could directly and significantly affect the design, conduct, or reporting of research or other activity that is sponsored by and extramural agency.

D. Financial Interest

Financial interest means anything of monetary value or potential monetary value, whether or not the value is readily ascertainable.

E. Investigator

Investigator means the project director or principal investigator/program director, co-investigator, collaborator, senior/key personnel, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting, of research that is sponsored by an extramural agency.

F. Institutional Official

Institutional Official means the individual with authority and responsibility for overseeing implementation of this policy and for ensuring consistent administrative review of Disclosure Statements. The Chief Financial Officer shall serve as the Institutional Official.

G. Institutional Responsibilities

Institutional responsibilities means an individual's professional responsibilities on behalf of PowerTech Water including, but not limited to, activities such as research, consulting for outside entities, teaching, professional practice, committee memberships, administration, extension or outreach, as well as service on institutional panels.

H. Manage

Manage means taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

I. Outside Entity

Outside entity means any entity recognized by law through which business for profit is conducted (including sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership or trust), or not-for-profit organization (including association, foundation, charitable organization, etc.).

J. Public Health Service (PHS)

Public Health Service (PHS) means an operating unit of the U.S. Department of Health and Human Services (HHS) that includes all PHS Awarding Components.

K. Remuneration

Remuneration means all salary and wages, including consulting fees, speaking fees, any payment for services not otherwise identified as salary or wages (e.g., honoraria, paid authorship, travel reimbursement, gifts), licensing revenue (e.g., royalty payments for inventions), royalties for books, publications or reports, or Equity Interests. Excluded from this definition is PowerTech Water salary.

L. Research

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research such as bench work, or other work and product development, and other forms of creative activity. The term includes any such research conducted by PowerTech Water personnel under the auspices of PowerTech Water, or conducted in situations in which PowerTech Water positions or titles are utilized in resultant publications, presentations, or other forms of intellectual property, irrespective of whether such research is funded by grant, contract, cooperative agreement, or gift. The term also includes collaborative work with a manufacturer, a distributor, or a sponsor of the research, and includes tangible or intangible inventions, discoveries, patents, or ideas necessary for development, utilization, or processes associated with the activity.

M. Significant Financial Interest

Significant Financial Interest means a financial interest consisting of one or more of the following interests of an Investigator or family member that reasonably appears related to the individual's institutional responsibilities:

1. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 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.
2. With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any

remuneration received from the entity during the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator or family member holds any equity interest in the entity.

3. A Significant Financial Interest includes any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests that when aggregated over the prior 12 months exceeds \$5,000.
4. For an Investigator who applies for or receives funding through a PHS grant, cooperative agreement, or contract, a Significant Financial Interest includes any reimbursed or sponsored travel (i.e., paid on behalf of the investigator rather than being reimbursed) that reasonably appears related to their institutional responsibilities and that when aggregated over the prior 12 months exceeds \$5000. Excluded is 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, or a medical center or a research institute that is affiliated with an institution of higher education.

Exclusions: The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by PowerTech Water to the Investigator or family member if the Investigator is currently employed or otherwise appointed by PowerTech Water; or income from service on advisory committees or review panels for a Federal, state, or local government agency.

For purposes of determining whether a financial interest is a Significant Financial Interest, financial interests across categories and family members must be aggregated. For example, if an Investigator has received a consulting fee of \$2,000 from a publicly traded entity, and a family member of the Investigator owns \$3,000 of equity interests in the same entity, the aggregate financial interest of the Investigator in the entity is \$5,000, which is a Significant Financial Interest.

N. Sponsored Agreement

Sponsored agreement means a grant, contract, cooperative agreement, and sub-agreements or subcontracts thereof.

V. Policy

- A. An individual covered by this policy shall complete, at least annually, a Financial Interests Disclosure Statement (Disclosure Statement) whether or not he or she has a financial interest to report. The Disclosure Statement shall include the financial interests of the Investigator and those of his or her spouse and dependent children.
- B. An individual required to disclose under this policy shall submit an updated Disclosure Statement within 30 days of acquiring a new financial interest that reasonably appears related to his or her institutional responsibilities.
- C. New employees who are required to disclose under this policy shall complete a Disclosure Statement within 30 days of their employment start date.
- D. An individual covered by this policy shall submit a Disclosure Statement prior to submitting a proposal seeking external funding, or prior to participating in any research activity regardless of the source of funding.
- E. Investigators who apply for or receive funding through a PHS grant, cooperative agreement, or contract, shall disclose instances of reimbursed or sponsored travel (i.e., paid on behalf of the Investigator rather than being reimbursed) that reasonably appears related to their institutional responsibilities and when aggregated exceeds \$5000 within 30 days of the completion of such travel.

- F. Disclosure Statements shall be reviewed by the Institutional Official or designee to assess whether or not a Significant Financial Interest constitutes a Financial Conflict of Interest.

VI. Disclosure Procedures

- A. Disclosures shall be made using a Disclosure Statement form that will be retained by the Institutional Official.
- B. Individuals required to disclose under this policy shall be notified during the month of February each year of the need to file a Disclosure Statement during the month of March.
- C. Individuals required to disclose under this policy to report a new financial interest may access the Disclosure Statement through the Institutional Official at any time in order to file an updated Disclosure Statement and to review their current Disclosure Statement.
- D. Individuals may access their Disclosure Statement history at any time.
- E. After completing a Disclosure Statement, the individual shall be required to certify that:
 - 1. The disclosure is accurate and complete to the best of their knowledge; and
 - 2. He/she/they agrees/agree to update their disclosure within thirty (30) days of acquiring a new financial interest that reasonably appears related to their institutional responsibilities.

VII. Disclosure Statement Review Procedures

- A. The Disclosure Statement review shall be done by the Institutional Official. Access to Disclosure Statements shall be restricted to those individuals authorized in writing by the Institutional Official.
- B. The review shall be the responsibility of the Institutional Official, who may delegate in writing to one or more persons day-to-day responsibility for reviewing Disclosure Statements. The Institutional Official will provide guidelines to assist the reviewer(s) in assessing whether or not a Significant Financial Interest appears to constitute a Financial Conflict of Interest. However, the Institutional Official shall be directly responsible for reviewing each Disclosure Statement where a real or perceived Financial Conflict of Interest appears to exist. The administrative review shall be completed within 60 days after the certified Disclosure Statement has been submitted.

The Institutional Official may involve the Investigator in the determination of whether a disclosed Significant Financial Interest is related to the Investigator's research or other sponsored project.

- C. If the administrative review reveals that the disclosed Significant Financial Interests do not represent a Financial Conflict of Interest, that determination shall be recorded, and no further action will be required.
- D. If a real or perceived Financial Conflict of Interest appears to exist, a Financial Conflict of Interest case number will be assigned, and the Institutional Official shall notify the Investigator for their review and input following procedures outlined in Section IX below.

The case shall be satisfactorily resolved and a final decision rendered by the Institutional Official before any funds may be expended from any related sponsored project award.

- E. No individual may participate in the administrative review of his/her/their own Disclosure Statement.

VIII. Management and Reporting of Financial Conflicts of Interest

- A. After being notified by the Institutional Official that a Financial Conflict of Interest appears to exist, they shall consult with the Investigator and the parties shall jointly review the Disclosure Statement.
 - 1. If the parties determine that no Financial Conflict of Interest exists, no further action will be required.
 - 2. If the parties determine that a Financial Conflict of Interest does exist, they may agree to eliminate the FCOI through divestiture of the Significant Financial Interest or severance of relationships. In this case, the Investigator shall provide a written copy of the agreement to the Institutional Official.
 - 3. If elimination of the Financial Conflict of Interest is not possible, the Investigator shall propose a course of action to manage or reduce the FCOI. The Institutional Official may assist with the plan. In any case, the Institutional Official shall review the proposed management plan.
- B. Once an appropriate management plan has been accepted by the Institutional Official, the Investigator shall file a report annually with the Institutional Official that documents the actions taken to implement the terms and conditions outlined in the plan. A final report shall also be submitted at the end of the project.

IX. Institutional Reporting Requirements and Record Retention

- A. The Institutional Official shall be responsible for institutional compliance with sponsoring agency reporting requirements.
- B. Disclosure Statements and other documentation used for the review of such statements and the records of any institutional actions taken pursuant to this policy shall be maintained by the Institutional Official for a period of three years. If the record is related to a research project or other sponsored agreement, the records shall be retained for a period of no less than three years following the date of submission of the final narrative and financial reports relating to such project or agreement, unless a longer record retention period is stipulated by the sponsor.
- C. To the extent permitted by law, such records shall be maintained confidentially.

X. Certification of Compliance

An individual required to disclose under this policy shall certify on the Internal Approval Form at the time of application for extramural support that he/she/they:

- A. Understands the requirements of this and related Governing Regulations and Administrative Regulations governing financial conflicts of interest.
- B. Has disclosed as of the date of the application all Significant Financial Interests that reasonably appear related to his/her/their institutional responsibilities; and
- C. At the conclusion of the review process, will comply with any conditions or restrictions imposed by the PowerTech Water to manage, reduce, or eliminate actual or potential financial conflicts of interest.

XI. Training

Pursuant to Federal regulations, the Institutional Official shall inform each Investigator about this policy and of his/her/their responsibilities to comply. Prior to engaging in sponsored research, each Investigator shall complete training regarding the disclosure of Significant Financial Interests and the management, reduction

or elimination of financial conflicts of interest. Training shall be repeated at least every four years or when (a) this policy is substantially revised; (b) an Investigator is new to PowerTech Water; or (c) if an Investigator is determined to not be in compliance with this policy.

XII. Enforcement

- A. The following acts and failures violate the provisions of this policy:
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.
- B. A violation of this policy is grounds for the discipline of an Investigator. Sanctions that may be imposed for such a violation include but are not limited to any one or more of the following:
1. Any Investigator who has not filed the required annual Disclosure Statement within 30 days of the end of the designated reporting period shall be administratively prohibited from applying for extramural support, including renewal of any active sponsored agreement, until the Disclosure Statement has been submitted and administratively reviewed.
 2. Any Investigator who fails to file the required annual Disclosure Statement within 60 days of the end of the designated reporting period, shall have his or her active research or other sponsored agreements suspended. No funds may be expended for any sponsored activity until the Disclosure Statement has been submitted and administratively reviewed.
 3. Involuntary termination of employment;
 4. Non-renewal of appointment;
 5. Suspension;
 6. Letter of admonition;
 7. Public disaffirmation of the research;
 8. Notification to regulatory bodies (e.g., U.S. Patent Office, Copyright Office);
 9. Notification to actual or potential research funding agencies; and
 10. Protest to editorial boards. Additionally, PowerTech Water may decline the sponsored research agreement, or decline to submit or further process any intellectual property.

XIII. Miscellaneous

- A. PowerTech Water shall make the information described in the preceding paragraphs 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, PowerTech Water 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.

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

References and Related Materials

- See the United States Department of Health and Human Services' Objectivity in Research Regulations 42 CFR Part 50 Subpart F (grants) ([click this link](#)) and 45 CFR Part 94 (contracts) ([click this link](#)).
- See the NIH's Office of Extramural Research Financial Conflict of Interest Web page: ([click this link](#)).
- See the NIH's Training About FCOIs: ([click this link](#)).
- See the Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interests and Foreign Components to determine if additional disclosures should be made at JIT or in the next progress report: ([click this link](#)).
- See NIH Other Support Information Page: ([click this link](#)).
- See NSF Current and Pending Support FAQs: ([click this link](#)).