

PFIC Network
Researcher Investigator and Reviewer
Conflict of Significant Financial Interest

Article I Purpose

The purpose of this policy is to promote objectivity in research by ensuring that the design, conduct, or reporting of funded research, grants, or cooperative agreements is free from bias resulting from an Investigator or Reviewer's financial conflicts of interest (FCOI). This includes conflicts related to the Investigator or Reviewer's spouse and/or dependent children.

Article II Scope

This policy applies to all Investigators involved in PFIC Network research. External partners functioning as Investigators must either certify compliance with the Public Health Services (PHS) FCOI Rules or follow PFIC Network's policy. Certification may be done via FDP COI Clearinghouse registration or written confirmation. Contract language will require adherence to this policy.

Article III Definitions

Investigator: Any individual responsible for the design, conduct, or reporting of research.

Reviewer: Individuals participating in the peer-review process to maintain scientific integrity.

Significant Financial Interest (SFI): A financial interest exceeding \$5,000, including remuneration, equity interests, or intellectual property rights that may impact research or would appear to do so to a reasonable person. It also includes reimbursed or sponsored travel related to institutional responsibilities, except when sponsored by government agencies, U.S. institutions of higher education, academic teaching hospitals, or research institutes. Exceptions include salaries paid by PFIC Network and income from governmental, academic, or medical institutions.

Article IV Policy and Procedures

Disclosure Requirements: Investigators/Reviewers must disclose all SFIs annually and within thirty (30) days of acquiring a new SFI. Disclosures must be updated as needed.

FCOI Review and Management: PFIC Network's FCOI Administrator reviews disclosures to determine relatedness to research. If the SFI is determined to be related to research, the institution will determine whether it constitutes a financial conflict of interest. Cases requiring

further review will be assessed by PFIC Network's Board or designated Committee, considering factors such as research integrity, conflict appearance, and risks to subjects. Management strategies may include public disclosure, independent monitoring, research plan modification, divestment, or reassignment. Any identified FCOI will be reported to the PHS funding agency prior to the expenditure of funds and updated annually or within sixty (60) days of new FCOI identification

Monitoring and Enforcement: Compliance with management plans will be monitored by the FCOI Administrator. Non-compliance may lead to disciplinary actions, including but not limited to termination of research involvement. Retrospective reviews will assess potential bias in research. If bias is found during a retrospective review, a mitigation report will be submitted to the PHS outlining corrective actions.

Training and Records: Investigators must complete FCOI training before engaging in research and every four years thereafter. Records related to disclosures and management plans will be maintained for at least three (3) years.

Public Accessibility: This policy is publicly available on PFIC Network's website. Requests for identified FCOIs of senior/key personnel will be responded to within five (5) business days.