

PUBLIC HEALTH SERVICE GRANTS

To promote objectivity in research, the following criteria for Financial Conflict of Interest (FCOI) must be met when applying for or using funds from a Public Health Service (PHS) grant or cooperative agreement for research.

Sub-grantees, contractors, or collaborators of a PHS-funded grant must have a policy in place that meets FCOI requirements. If there is no policy in place, it must be contained in a written agreement that the sub-grantee/contractor/collaborator will follow all requirements for an investigator in this policy.

A. Disclosure of Significant Financial Interest (SFI)

- Investigators (i.e., anyone responsible for the design, conduct, or reporting of research funded by PHS) and their spouse and dependent children must disclose any SFI related to the Investigator's grant responsibilities:
 - No later than at the time of application for PHS-funded research
 - At least annually during the period of the grant
 - Within 30 days of discovering/acquiring a new SFI
- SFI is anything of monetary value, including:
 - Non-Department salary or other payment for services (e.g., consulting fees, honoraria)
 - Equity interests (e.g., stocks, stock options, other ownership interests)
 - Intellectual property rights (e.g., patents, copyrights, royalties from rights)
- The Grant Administrator will review disclosure of SFIs, determine if an SFI is related to the PHS-funded research, and if it would result in an FCOI:
 - Before expenditure of any funds
 - When an Investigator is a new participant
 - When a new SFI is being reported

B. Identified FCOI

- When FCOI is determined to be present, the Grant Administrator will:
 - Develop and implement a management plan within 60 days that includes actions necessary to monitor and ensure Investigator compliance until completion of the project
 - Send initial, annual/ongoing, and revised FCOI reports to the National Institute of Health (NIH):
 - * Before expenditure of funds
 - * Within 60 days of determining FCOI exists
 - * To provide status of an FCOI or changes to a management plan
 - Immediately notify the NIH if:

- * Bias is found with design, conduct, or reporting of NIH-funded research and submit a Mitigation Report
- * An Investigator fails to comply with this policy or a management plan

C. Noncompliance

- Corrective action will be taken immediately, up to and including dismissal, for employees/contract staff if it is determined they are out of compliance with this policy.
 - A review will be conducted and documented within 120 days of determination that an employee/contract staff is not compliant with disclosing SFI or the requirements of a management plan
 - Investigators determined to be out of compliance will disclose the FCOI in each public presentation of the results of the research, and will request an addendum to previously published presentations

D. FCOI Training:

- Investigators will be provided with this policy and must complete FCOI training:
 - Before engaging in research related to any PHS-funded grant
 - At least every 4 years
 - Immediately when:
 - * New to the Department
 - * This policy is revised
 - * Determined to be out of compliance

E. Documentation

- The Grant Administrator will:
 - Maintain all FCOI-related documentation per 42 CFR 50
 - Post any newly identified FCOI to the Department's external website within 60 days and update the information at least annually