

Appendix to the Policy on Financial Conflicts of Interest and Research: FCOI Reporting & Recordkeeping for PHS-Funded Research

This Appendix codifies the University's implementation of the Public Health Service ("PHS") regulations pertaining to financial conflicts of interest ("FCOI"), including 42 C.F.R. Part 50, Subpart F, and 45 C.F.R. Part 94.

A. Reporting to the PHS Awarding Component

1. FCOI identified *before* expenditure of funds:

Where a conflict of interest related to a PHS-funded award is identified before the award is set up, award set-up will not be finalized until the University's Office of Sponsored Projects Administration (SPA) has reported to the PHS Awarding Component that the conflict of interest has been managed, reduced, or eliminated.

2. FCOI identified *after* expenditure of funds:

In the event that a conflict of interest related to a PHS-funded award is identified subsequent to expenditure of funds on an award, SPA will report to the PHS Awarding Component that such subsequently identified conflict has been reduced, managed or eliminated, at least on an interim basis, within 60 days of identification.

3. Investigator Non-Compliance and Bias:

In the event that an individual's failure to comply with the University's Policy on Financial Conflicts of Interest and Research has biased the design, conduct, or reporting of PHS-funded research, SPA will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

4. Sub-recipient Reporting:

In accordance with its subrecipient agreements, the University expects subrecipients to comply with PHS regulations pertaining to FCOI, including regulations concerning subrecipient reporting obligations. In the event that a sub-recipient notifies the University of a conflict of interest for a sub-recipient employee participating in a PHS-funded project for which the University is the prime awardee, the University will promptly notify the PHS Awarding Component.

B. Maintenance of Records

1. In the event that an actual or potential FCOI has been identified in connection with PHS-funded research, records of all financial disclosures and all actions taken by the Committee on Financial Conflicts of Interest and Research related to the identified conflict will be retained for at least three years from the date of submission of the final expenditure report to the sponsoring agency or agencies, or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report.
2. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.