

Addendum to Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects for Research funded by the United States Public Health Service and sponsors requiring adherence to PHS rules

PURPOSE

This Addendum modifies the requirements for disclosure of financial interests related to sponsored projects for submission of proposals to, and conduct of sponsored research funded by, the United States Public Health Service (PHS) and any sponsor requiring adherence to PHS rules on disclosure of financial conflicts of interest.

BACKGROUND

In contrast with general requirements for sponsored research, PHS rules require:

- A threshold (“de minimus”) of \$5,000 for a source of income to give rise to a financial conflict of interest requiring reporting and elimination or management.
- That each Investigator (each individual having independent responsibility for the design, conduct or reporting of results of a project) disclose sources of income, holdings, roles and relationships that could be viewed as affecting the conduct of **any** of the Investigator’s responsibilities at Lehigh University.
- That the university (not the Investigator) determine whether any of these sources of income, holdings or relationships apply under the PHS rules to the sponsored project.
- That in addition to reporting the fact of any conflict to the sponsor and certify that it is being managed, the university disclose to the sponsor and to members of the public in response to specific requests, for senior and key personnel on projects, the nature of the conflict including the approximate dollar values of income, sources and holdings. Response to a request from a member of the public must occur within five working days of the request.
- That each Investigator demonstrate an understanding of the Investigator’s responsibilities in compliance with the PHS rules.

For reference, see 42 CFR Part 50 and 45 CFR Part 94 at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf> and the FAQ at http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

POLICY

1. Upon submission of a proposal to PHS or to any sponsor requiring compliance with PHS rules on financial conflicts of interest, each of the listed Key Personnel and each person having independent responsibility for the design, conduct or reporting of results of a project must provide to the Office of Research and Sponsored Programs a completed **PHS-Funded Project Financial Interests Report**, following the instructions and applying the definitions provided on the reporting form. The reporting form must be re-filed annually or within 30 days of occurrence of any change in any of the responses.
2. Upon submission of a proposal to PHS or to any sponsor requiring compliance with PHS rules on financial conflicts of interest, each of the listed Key Personnel and each person having independent responsibility for the design, conduct or reporting of results of a project must have successfully completed training in the PHS rules as designated by the Director of the Office of Research and Sponsored Programs, and must provide evidence of successful completion to the Office of Research and Sponsored Programs.
3. The Director of the Office of Research and Sponsored Programs, in consultation with the Director of Internal Audit will review the responses and determine whether a financial conflict of interest exists under PHS rules and will, notify the faculty or staff member of the determination, and will provide required notice to the sponsor with a copy provided to the affected individual.
4. Responses to public requests will be provided in a timely fashion as required by law. The affected individual will be promptly notified of the request and the university's obligation to comply and will be provided with a copy of the university's response.
5. Other than as provided in items 2 and 3 above, confidentiality of information disclosed as described in the Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects shall apply.
6. Financial conflicts of interest shall be managed as described in the Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects.

OTHER DOCUMENTS

University Conflict of Interest Policy, Policy on Disclosure of Investigator Significant Financial Interests in Sponsored Projects and Addendum for projects sponsored by the U.S. Public Health Service
<https://research.cc.lehigh.edu/research-integrity>

HISTORY

Addendum to 06-Nov-2008 policy.