

§ 50.605 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

- (1) Public disclosure of significant financial interests;
- (2) Monitoring of research by independent reviewers;
- (3) Modification of the research plan;
- (4) Disqualification from participation in all or a portion of the research funded by the PHS;
- (5) Divestiture of significant financial interests; or
- (6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

§ 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the

PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

§ 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart.

They include, but are not necessarily limited to:

- 42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure
- 45 CFR Part 16—Procedures of the Departmental Grant Appeals Board
- 45 CFR Part 74—Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments
- 45 CFR Part 76—Government-wide debarment and suspension (non-procurement)
- 45 CFR Part 79—Program Fraud Civil Remedies
- 45 CFR Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

2. A new part 94 is added to 45 CFR, subtitle A, to read as follows:

PART 94—RESPONSIBLE PROSPECTIVE CONTRACTORS

Sec.

- 94.1 Purpose.
- 94.2 Applicability.
- 94.3 Definitions.
- 94.4 Institutional Responsibility Regarding Conflicting Interests of Investigators.
- 94.5 Management of Conflicting Interests.
- 94.6 Remedies.

Authority: 42 U.S.C. 216, 289b–1, 299c–3.

§ 94.1 Purpose.

This part promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed

under PHS contracts will be biased by any conflicting financial interest of an Investigator.

§ 94.2 Applicability.

This part is applicable to each Institution that seeks PHS funding for research and, through the implementation of this part, to each Investigator who participates in such research (see § 94.4(a)); provided that this part does not apply to SBIR Program Phase I applications.

§ 94.3 Definitions.

As used in this part:

Contractor means an entity that provides property or services for the direct benefit or use of the Federal Government.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any public or private entity or organization (excluding a Federal agency)

(1) That submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or

(2) That assumes the legal obligation to carry out the research required under the contract.

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of a research project funded by PHS, or proposed for such funding. For purposes of the requirements of this part relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

Public Health Service Act or *PHS Act* mean the statute codified at 42 U.S.C. 201 *et seq.*

PHS Awarding Component means an organizational unit of the PHS that funds research that is subject to this part.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this part, the term includes any such activity for which funding is available from a PHS Awarding Component, whether