

Department of Health and Human Services

§ 94.3

AUTHORITY: 42 U.S.C. 216, 289b-1, 299c-3.

SOURCE: 60 FR 35817, July 11, 1995, unless otherwise noted.

§ 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.

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

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

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 authorized under the PHS Act or other statutory authority.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents copyrights and royalties from such rights). The term does not include:

(1) Salary, royalties, or other remuneration from the applicant institution;

(2) Any ownership interests in the institution, if the institution is an applicant under the SBIR program;

(3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(4) Income from service on advisory committees or review panels for public or nonprofit entities;

(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

(6) Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the

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next twelve months, are not reasonably expected to exceed \$10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

§ 94.4 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this part and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subcontractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this part, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this part.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS, each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) that would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) in entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award,

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either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this part for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for three years after final payment or, where applicable, for the other time periods specified in 48 CFR part 4, subpart 4.7.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each contract proposal, that:

(1) there is in effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of any conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accordance with this part; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

(3) the Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with this part.

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