

§ 94.1

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

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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