

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Public Health Service****42 CFR Part 50****Office of the Secretary****45 CFR Part 94**

RIN 0905-AE01

**Objectivity in Research**

**AGENCY:** Public Health Service and Office of the Secretary, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Public Health Service (PHS) and the Office of the Secretary, HHS, are promulgating regulations establishing standards and procedures to be followed by institutions that apply for research funding from the PHS to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research.

Under the rules, investigators are required to disclose to an official(s) designated by the institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding by the PHS. The institutional official(s) will review those disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research and, if so, the institution must, prior to any expenditure of awarded funds, report the existence of such conflicting interests to the PHS Awarding Component and act to protect PHS-funded research from bias due to the conflict of interest.

**EFFECTIVE DATE:** October 1, 1995.

**FOR FURTHER INFORMATION CONTACT:** Dr. George J. Galasso, Associate Director for Extramural Affairs, National Institutes of Health, Building 1, Room 552, 9000 Rockville Pike, MSC 0154, Bethesda, MD 20892-0154. The telephone number is (301) 496-5356 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** On June 28, 1994 the Department of Health and Human Services (HHS) published proposed regulations (59 FR 33242) to ensure that PHS-funded research would not be compromised by financial interests of investigators that could be reasonably expected to bias the design, conduct or reporting of the research. In

addition to setting forth proposed rules requiring institutional procedures for the disclosure and management, reduction or elimination of Significant Financial Interests that would reasonably appear to be directly and significantly affected by the research funded by PHS, or proposed for funding, the Notice of Proposed Rulemaking (NPRM) raised several specific questions about alternatives for implementing the pertinent statutes and for ensuring that PHS-funded research is not compromised by any financial conflicts of interest.

The NPRM was published in the **Federal Register** at the same time the National Science Foundation (NSF) published its Investigator Financial Disclosure Policy and reflected coordination between the two agencies. Since that time, we have continued to work closely with the NSF to ensure that the NSF policy and our regulations do not impose disparate requirements upon the many institutions that receive funding from both agencies. Elsewhere in this separate part in this **Federal Register**, the NSF is issuing changes in its policy necessary to maintain consistency with this final rule, and the changes we have made to conform to the NSF policy are referenced in the discussion that follows. The agencies intend to continue their cooperation by working together to develop common guidance, including a set of questions and answers, to help institutions implement conflict of interest policies that comply with both HHS and NSF requirements.

During the 60 day comment period that ended on August 28, 1994, the PHS received 102 comments on the NPRM. Most of the comments were generally supportive of giving the applicant institutions primary responsibility for identifying and resolving financial conflicts of interest that could directly and significantly affect the PHS-funded research. The comments are summarized below under the headings: Changes in the NPRM; Comments Not Resulting in Any Changes; and Responses to Questions on Alternatives.

**Changes in the NPRM**

A summary of the changes made in the regulations as proposed on June 28, 1994, follows.

1. In the section titles, §§ 50.601, 50.602, 50.605 and several other sections,<sup>1</sup> references to "Significant Financial Interests" or "Significant

<sup>1</sup> Only the sections in 42 CFR part 50 are referenced. Similar changes have been made in the regulations at 45 CFR part 94 which will apply to contracts.

Financial Interests of the type described in § 50.605," have been changed to refer to a conflict of interest or conflicting financial interests. This change has been made in response to many of the comments. It was pointed out that this change will make the HHS regulations consistent with the NSF regulations and that the institutions can only manage the conflict, not the financial interests.

2. In response to several comments, the "Purpose" sections in the grants and the contracts regulations have been rewritten to make them more concise and parallel.

3. A reference to § 50.604(a) has been added to the "Applicability" section. As explained more fully in paragraph 6 below, this change and the change in § 50.604(a) clarify that the regulations apply to Investigators carrying out the PHS-funded research for subgrantees or contractors of the awardee institution.

4. In response to several comments, the definition of "Investigator," has been amended to delete the phrase "at the Institution."

5. The definition of "Significant Financial Interest" in § 50.603 has been changed in several respects. Clause (i) has been split so that ownership interests are now referenced in a new clause (ii). Some commenters felt that it was not clear whether the requirement that an institution be an applicant under the SBIR program modified both ownership interest and salary, royalties or other remuneration.

The exception for financial interests in business enterprises has been split to clarify that the per annum measurement applies only to salary, royalties or other payments not reasonably expected to exceed \$10,000 per annum. In addition, the dollar limits have been changed from \$5,000 to \$10,000 and the applicability of the alternative measures of \$10,000 in value or five percent ownership interest, has been clarified. These changes have been made in response to a large number of comments stating that the \$5,000 limit was too low. A majority of those comments indicated that \$10,000 would be an appropriate figure, particularly since the experience of state universities in California, and some other universities, is that interests up to this amount do not raise conflict of interest concerns.

The reference to determining the value of equity interests on the basis of public prices or other reasonable measures of fair market value was adapted from a similar provision in the proposed FDA rule on conflict of interest (59 FR 48708 *et seq.*, September 22, 1994).

6. Section 50.604(a) has been revised to clarify that the Institution must