

reporting and recordkeeping requirements, not all activities of an institution that may result from the regulations.

Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought.

Description: The regulations would require each applicant/offeror Institution to establish procedures to identify and manage, reduce, or eliminate any conflicting financial interest of an Investigator involved in the design, conduct or reporting of the

research for which PHS funding is sought.

Description of Respondents: Public and private non-profit institutions, small business, and other for-profit organizations and investigators working for such institutions, businesses and organizations.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Applicable section of regulation 42 CFR	Applicable section of regulation 45 CFR	Total number of respondents	Mean hours per response	Total hours 42 CFR	Total hours 45 CFR	Total hours
Reporting:						
50.604(g)(2) (initial report of conflict of interest)	94.4(g)(2)	200	80.0	14,000	2,000	16,000
50.604(g)(2) (subsequent reports of conflict of interest).	94.4(g)(2)	30	2.0	54	6	60
50.606(a)	94.6(a)	5	10.0	40	10	50
Total						16,110
Recordkeeping:						
50.604(e)	94.4(e)	20,000	4	72,000	8,000	80,000
Total						80,000
Disclosure:						
50.604(a)	94.4(a)	2,000	20.0	36,000	4,000	40,000
50.604(c)	94.4(c)	35,000	1	31,600	3,400	35,500
Total						75,000
Total Burden						171,110

In accordance with the requirements of the Paperwork Reduction Act of 1980, the Department of Health and Human Services has submitted the information collection requirements cited above to OMB for review and approval. Organizations and individuals desiring to submit comments on the information collection requirements and the estimated burden should direct such comments to the information address cited above and to: NIH/PHS Desk Officer, Office of Information and Regulatory Affairs, OMB, New Executive Office Building, room 10235, 725 17th Street NW., Washington, DC 20503.

Catalogue of Federal Domestic Assistance

The rule will affect all extramural research, research and development, and research and development support funded by the Public Health Service. Questions about the rule should be directed to Dr. George J. Galasso, Associated 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).

List of Subjects

42 CFR Part 50

Grant programs—health; Conflict of interest; Medical research; Behavioral, biological, biochemical, psychological and psychiatric research.

45 CFR Part 94

Government procurement.

Dated: March 13, 1995.

Philip R. Lee,

Assistant Secretary for Health.

Approved: May 17, 1995.

Donna E. Shalala,

Secretary.

Accordingly, 42 CFR part 50 and 45 CFR subtitle A are amended as set forth below:

1. Subpart F is added to 42 CFR part 50 to read as follows:

Subpart F—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

Sec.

50.601 Purpose.

50.602 Applicability.

50.603 Definitions.

50.604 Institutional responsibility regarding conflicting interests of investigators.

50.605 Management of conflicting interests.

50.606 Remedies.

50.607 Other HHS regulations that apply.

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

Subpart F—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

§ 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.

§ 50.602 Applicability.

This subpart is applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through the implementation of this subpart by each Institution, to each Investigator participating in such research (see § 50.604(a)); provided, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an institution, is an applicant for PHS grants or cooperative agreements for research, PHS Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any conflicting financial interest of the individual.