SUPPORTING STATEMENT
FOR

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought
42 CFR Part 50 Subpart F and
Responsible Prospective Contractors (OD)
45 CFR Part 94
OMB No. 0925-0417

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A. Justification

1. . Circumstances Making the Collection of Information Necessary

This request is for OMB approval of an extension of a currently approved collection regarding the **Responsibility of Applicants for Promoting Objectivity in Research** for which PHS Funding is Sought and information collection and record keeping requirements contained in the final rule at 42 CFR §50.601 et sec. and Responsible Prospective Contractors, 45 CFR Part 94. (hereinafter regulations).

Given the increasing complexity of financing biomedical research, the Public Health Service (PHS) and the Office of the Secretary of Health and Human Services (HHS) published two regulations in 1995 establishing standards and procedures to be followed by institutions that apply for research funding from PHS agencies, including the NIH. [1] The regulations are aimed at ensuring that the design, conduct, or reporting of research publically funded under grants, cooperative agreements, and contracts will not be biased by any conflicting financial interest of an investigator.

[1] The regulation is applicable to each Institution that applies for NIH grants and cooperative agreements for research or submits a proposal for a research contract whether in response to a solicitation or otherwise and, through implementation of the regulation by each Institution, to any Investigator participating in that research. An Institution is defined as any domestic or foreign, public or private, entity or organization (excluding a Federal agency). This regulation does not apply to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) program applications or awards. NIH is responsible for the largest share of public health research funding.

The regulations require Investigator's to disclose their "Significant Financial Interests" (as defined in the regulation) that would reasonably appear to be affected by the research for which PHS funding is sought and in entities whose financial interests would reasonably appear to be affected by the research. A conflict of interest exists when the institutional official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The institutional official(s) solicits and reviews Investigators' Significant Financial Interests, identifies conflicting interests, and takes such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated to protect PHS-funded research from any bias.

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. The HHS may at any time inquire into the institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including requirements for submission of, or review on site, of all records pertinent to compliance with the regulations. 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 the regulations.

When issued, the regulations met the requirements originally set forth in the NIH Revitalization Act of 1993, P. L. 103-43, Section 164, Requirement of Regulations

Regarding Protection Against Financial Conflicts of Interest in Certain Projects of Research. Public. On January 15, 2007, the President signed H.R. 6164 as P.L. 109-482, the National Institutes of Health Reform Act of 2006, affirming the importance of NIH and its vital role in advancing biomedical research to improve the health of the Nation. Additional authority for the regulations derive from Section 216 of the PHS Act authorizing the Assistant Secretary for Health, with the approval of the Secretary, to promulgate regulations necessary for the administration of the Public Health Service. Additional authority also derives from 42 U.S.C. §289b-1, "Protection against financial conflicts of interests in certain projects of research" and 42 U.S.C. §299c-4, "Additional Provisions with respect to grants and contracts" which authorizes the Director by regulation to "define the specific circumstances that constitute financial interests …that will, or may be reasonably expected to create a bias in favor of obtaining results in the projects that are consistent with such interests." 42 U.S.C. §299c-4(a)(1). Further authority for the regulations and this information collection is found in 5 U.S.C. §301, the Secretary's general authority to issue regulations necessary for the administration of the Department.

As noted in the Notice of Proposed Rulemaking – Objectivity in Research, (republished in the NIH GUIDE, Volume 23, Number 25, July 1, 1994), numerous statutes and programs demonstrate a continuing Federal interest in the promotion of interactions between Government, academia, and industry. For example, the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480) encourages technology transfer, particularly through industrial-academic collaborations. The Patent and Trademark Act Amendments of 1980 (P.L. 96-517) allow universities and other award recipients to apply

for patents developed with Federal funding (rather than awarding such rights to the Government), and expressly promote collaboration between commercial concerns and nonprofit organizations. The Economic Recovery Tax Act of 1981 (P.L. 97-34) is aimed at fostering research and development by small companies and associated university partners. The Federal Technology Transfer Act of 1986 (P.L. 99-502), which amended P.L. 96-480, and Executive Order 12592 provide similar patent and licensing authority to Federal laboratories and encourage them to participate in cooperative research and development agreements with the private sector and nonprofit organizations, including universities." The Notice of Proposed Rulemaking also noted that "[t]hese and other inducements for collaboration, as well as the rapid growth of the biotechnology industry have created a climate in which the stewardship of public funding for biomedical and behavioral research is increasingly complex and challenging." Due to evolving nature and complexity of funding for biomedical research, the stewardship challenges have only increased for PHS Awarding Components since the regulations became effective. Although the regulatory requirements imposed upon PHS awardees are longstanding, the world of scientific collaboration has become more complex and new types of relationships are emerging and with them the increased potential for conflicts of interest. In light of these evolving financial relationships, institutions and contracting organizations that receive PHS support to conduct research must continue to identify and manage the conflicts of interest of all PHS-supported investigators and to comply with the associated reporting requirements. See Question B. 6. in Frequently Asked Questions posted on the NIH website, regarding "*What must the Institution report to the NIH and when should it be reported*?"

The Code of Federal Regulations (CFR) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding Is Sought and 45 CFR Part 94, Responsible Prospective Contractors, promote objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, and contracts will not be biased by a conflicting financial interest of an "investigator." The regulations define "investigator" as the principal investigator and any other person who is responsible for the design, conduct, or reporting of funded research, and for purposes of the regulations, includes the investigator's spouse and dependent children (42 CFR § 50.603 and 45 CFR § 94.3). The regulations require that institutions seeking PHS support for research have written, enforced administrative process to identify and manage, reduce, or eliminate conflicting interests. Institutions must inform investigators of the conflict of interest policy, the regulations, and of their individual reporting responsibilities. The regulations promote objectivity in research by establishing standards "to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator" NIH Grants Policy Statement, December 1, 2003, pps. 44-46 (Attachment 1).

We request approval for the continuation of the following information collection and recordkeeping requirements set forth in the regulation 42 CFR Part 50, Subpart F and 45 CFR Part 94.

Reporting

Section 50.604(g)(2) and 94.4(g)(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 a 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 subpart; 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.”

Section 50.606(a) and 94.6(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.”.

Recordkeeping

Section 50.604(e) and 94.4(e):

Each Institution must “maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditure report or final payment or, where applicable,

from other dates specified in 42 CFR 74.53(b) [and 48 CFR Part 4, Subpart 4.7] for different situations."

Disclosure
Section 50.604(c)(1) and 94.4(c)(1):

Each Institution "must require that by the time an application is submitted to the PHS, each Investigator who is planning to participate in the PHS-funded research must submit to the designated official 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."

Section 50.604(c)(2) and 94.4(c)(2):

Requires that "[a]ll financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained."

2. <u>Purpose and Use of the Information Collection</u>

When an Institution seeks research funds for PHS grants, cooperative agreements, or contracts the Institution certifies in the application or contract proposal that "[t]here is [i]n 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." §50.604(g)(1). Moreover, Institutions are required to certify compliance with all aspects of the regulation, including that Investigators are informed of the Institutional policy, their reporting responsibilities, and of the regulations. The disclosure of certain Significant Financial Interest information by

Investigators to designated Institutional officials is necessary to ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contractors will be biased by any conflicting financial interest of an Investigator. The Significant Financial Interest information disclosed by the Investigators to the designated Institutional officials remains at, and under the control of, the Institutions.

As previously described, Institutions are required to report the existence of conflicts of interests to PHS Awarding Components and that those conflicts are being managed, reduced, or eliminated. Within the NIH, each funding Institute/Center, is the official receipt point for financial conflict-of-interest reports. For grants, NIH requires that all conflict of interest reports be sent to the appropriate Chief Grants Management Officer (CGMO) of the NIH funding Institute/Center, (http://grants.nih.gov/grants/stafflist_gmos.htm.) For contracts, awardees are instructed to send reports to the appropriate Director, Office of Acquisitions, (http://oamp.od.nih.gov/AcquisitionOffices/chief_cos1.asp).

Awarding PHS Components (at NIH, Institutes/Centers) may inquire, as necessary, about all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias, and Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission, or review on site, all records pertinent to compliance with the regulations. In all such inquiries, PHS Awarding Components maintain strict confidentiality of all Institutional records to the maximum extent permitted by law.

3. Use of Information Technology and Burden Reduction

This collection does not involve the use of any forms. Current instructions to Institutions on what must be reported and what reports should include are posted on the NIH webpage. http://grants.nih.gov/grants/policy/coifaq.htm#b6 and http://grants.nih.gov/grants/policy/coifaq.htm#b7. NIH is presently identifying ways to reduce the recordkeeping and reporting burdens on the Institutions. NIH is developing a module in its Electronic Research Administration (eRA) Commons that will allow recipient institutions to electronically submit required reports. The eRA Commons is NIH's electronic interface with extramural grantee organizations, supporting the full life cycle of a grant. At the present time, NIH does not anticipate that electronic reporting would produce any significant reduction in the approved total annual burden hours. The record keeping aspects of the regulations are the most significant aspect of the total approved annual burden because they involve information gathering from Investigators and maintenance of institutional files (See Estimate of Burden Hours). However, as the eRA Commons module is developed, NIH will continue to review the impact of the application of this technology on the total approved annual burden for this collection and will request revisions in approved burden hours as appropriate.

4. Efforts to Identify Duplication and Use of Similar Information

There are no reporting requirements included in the estimate of the burden that duplicate existing requirements. There are no similar data available.

5. Impact on Small Businesses or Other Small Entities

This regulation and accompanying record keeping, reporting and disclosure burdens do not apply to Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Program Phase I applications.

6. Consequences of Collecting the Information Less Frequently

Objectivity in research is important throughout the award period. The regulations establish the frequency and timing of the record keeping, reporting and disclosure. See above response to A.1 and Attachment 2, Instructions to Respondents. Reduced frequency would have an adverse impact the ability of PHS Awarding Components to monitor compliance with the regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection is consistent with the requirements of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In compliance with 5 CFR §1320.8 (d), soliciting comments on the information collection prior to submission to OMB, the 60-day Federal Register Notice was published on July 14, 2008, pages 40354–40355 . No public comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information collected by each applicant Institution will be kept in accordance with the procedures for confidentiality of each applicant Institution. The information reported

to the PHS will be available only to staff of the PHS responsible for the administration of grants, cooperative agreements, and contracts. As part of official award files, the information collected will be subject to the provisions of the Privacy Act. See Notice for the Extramural Awards System of Records: Federal Register, Vol. 67, No.187, pages 60751-60752, September 26, 2002. 09-25-0036.

11. Justification for Sensitive Questions

In accordance with Public Law 103-43, Section 164, as it establishes Section 493A of the Public Health Service Act and, in particular, Section 493A (a)(2), 42 U.S.C. 289b-1, an Institution might be required to provide information to the PHS about the disclosed significant financial interests of individuals who are employed by that Institution and are conducting research funded by the PHS. The information reported to the PHS is subject to the provisions of the Privacy Act.

12. Estimates of Annualized Burden Hours and Costs

When this information collection was initially approved in 1995, no systematic data existed regarding the incidence of Financial Conflicts of Interests of Investigators in PHS-funded research. Estimates of the burden were based on the number of applications and proposals received per year by the PHS, and were refined following communication with applicant organizations. An estimate of the average burden per application or proposal is used to calculate the following estimates. The estimate for the annual respondent burden is set forth in the following table. The estimated total annual burden is 220,280 hours.

Table A.12 - 1 ESTIMATES OF HOUR BURDEN

Type of Respondents Based on Applicable Section of Regulation	Number of Respondents	Frequency of Response	Average Burden Hours per Response	Annual Hour Burden
Reporting				
Initial Reports under 42 CFR §50.604 (g)(2) or 45 CFR 94.4(g) (2) from Institutions	300[i]	1	80 Hours	24000
Subsequent Reports under 42 CFR §50.604 (g) (2) or 45 CFR 94.4(g)(2) from Institutions	40[II]	1	2 Hours	80
Subsequent Reports under 42 CFR §50.606 (a) or 45 CFR 94.6 from Institutions	20[III]	1	10 Hours	200
Record Keeping				
Under 42 CFR §50.604 (e) or 45 CFR 94.4 (e) – Institutional files	25000[IV]	1	4 Hours	100000
Disclosure				
Under 42 CFR §50.604(a) or 45 CFR 94.4 (a) - Institutions	2800[V]	1	20 Hours	56000
Under 42 CFR §50.604(c) or45 CFR 94.4 (c) - Investigators	40000[VI]	1	1 Hour	40000
Totals	**68160**			**220280**

13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

Operating Costs, and/or Maintenance Costs are $4,633.

14. Annualized Cost to the Federal Government

The estimated annual cost to the Government of these regulations includes the management of reports from institutions: 1) of identified conflicts of interest submitted prior to the Institution's expenditure of any funds under an award (Initial Report), 2) of conflicts of interest identified after the Initial Report submitted within sixty days of the identification, 3) that an Investigator's failure to comply with the Institution's conflict of interest policy has biased the design, conduct, or reporting of PHS-funded research, and 4) in response to the government's request for additional information.

In this extension, and in previous extensions, of this Information Collection Request, the cost to the government has been estimated based upon the receipt of approximately 300 initial reports and 60 subsequent reports on an annual basis. In this extension, and in previous extensions, it has been anticipated that the Government involvement may vary considerably from case to case. On average, each case would require 40 hours spent on review, correspondence, and record keeping. Estimating 20 hours effort per case by senior officials at $55.00/hour and 20 hours effort per case by support staff at $12.00/hour, the annual cost to the Government is $482,400.

As the eRA Commons module is developed for electronic submission of required reports, NIH will be able to refine the estimated costs to the government in future extensions of

this ICR based upon its ability to more accurately determine the number of annual reports it receives and the complexity of the reviews.

15. Explanation for Program Changes or Adjustments

The estimated total annual burden hours has been reduced from 232,000 to 220,080. This downward adjustment is due solely to a miscalculation discovered in prior estimates. There are no other program changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will be used to update the estimate of the record keeping burden.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

While there are no forms associated with this collection, the expiration date for OMB approval of the information collection will be displayed on appropriate PHS Component web sites.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19, "Certification for paperwork Reduction Act Submissions," for OMB Form 83-I.

B. Statistical Methods

This collection of information does not employ statistical methods.

While there are no forms associated with this collection, the expiration date for OMB approval of the information collection will be displayed on appropriate PHS Component web sites.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19, "Certification for paperwork Reduction Act Submissions," for OMB Form 83-I.

B. Statistical Methods

This collection of information does not employ statistical methods.