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
45 CFR Part 94
OMB No. 0925-0417

December 2011

Diane W. Dean
6705 Rockledge Drive, Suite 350
Bethesda, MD 20892
Phone: 301-435-0930
Fax: 301-435-3059
Email: deand@od.nih.gov

Table of Contents

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
45 CFR Part 94
OMB No. 0925-0417

A. Justification

1. Circumstances Making the Collection of Information Necessary

This request is for Office of Management and Budget (OMB) approval of a revision of a currently approved collection resulting from the development of revised regulations regarding the **Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought** (42 CFR Part 50, Subpart F) and **Responsible Prospective Contractors (**45 CFR Part 94).

In 1995, the PHS and the Office of the Secretary of HHS published regulations at 42 CFR Part 50, Subpart F and 45 CFR Part 94 (the 1995 regulations), that are designed to promote objectivity in PHS-funded research. The 1995 regulations cover Institutions that apply for or seek PHS funding for research (except for Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications) and, through implementation of the regulations by these Institutions, to each Investigator participating in the research.

The purpose of the 1995 regulations was to ensure that there is no reasonable expectation that the design, conduct, or reporting of PHS-funded research will be biased by any Investigator financial conflict of interest (FCOI).

Since the publication of the 1995 regulations, the growing complexity of biomedical and behavioral research; the increased interaction among Government, research Institutions, and the private sector in attaining common public health goals while meeting public expectations for research integrity; as well as increased public scrutiny, all have raised questions as to whether a more rigorous approach to Investigator disclosure, institutional management of financial conflicts, and federal oversight is required. HHS decided to explore the need for revisions to the 1995 regulations by publishing an Advance Notice of Proposed Rulemaking on May 8, 2009 (74 FR 21610, hereafter "the ANPRM").

After analyzing public comments, HHS published a Notice of Proposed Rulemaking (75 FR 28688, hereafter "the NPRM") on May 21, 2010, to amend the 1995 regulations by expanding and adding transparency to Investigators' disclosure of significant financial interests (SFIs), enhancing regulatory compliance and effective institutional oversight and management of Investigators' FCOIs, as well as HHS' compliance oversight.

On July 21, 2010, HHS published a Notice (75 FR 42362, hereafter "the Extension Notice") extending the 60 day comment period for the NPRM by another 30 days and seeking comment on whether HHS should clarify its authority to enforce compliance with the regulations by Institutions and Investigators, and whether HHS should clarify how the regulations apply in circumstances in which an Investigator or a PHS-funded research project transfers from one Institution to another.

After considering all public comments, and consistent with the proposals articulated in the NPRM, HHS has developed the final rule, which includes the following major changes to the 1995 regulations:

- Amending the definition of SFI to include a de minimis threshold of $5,000 for disclosure that generally applies to payments for services and/or equity interests as well as any equity interest in non-publicly traded entities.
- Excluding income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Expanding Investigator disclosure requirements to include SFIs that are related to an Investigator's institutional responsibilities, with Institutions responsible for determining whether a disclosed SFI relates to the research for which PHS funding is sought and whether it constitutes an FCOI. Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to their Institutional responsibilities for considerations by the Institutional official(s). The requirement to "disclose" information about Investigator sponsored travel or reimbursed travel (but not dollar amounts) does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Enhancing the information on an FCOI reported by the Institution to the PHS funding component to include the information required under the 1995 regulations plus the value of the financial interest, or a statement that a value cannot be readily determined, the nature of the FCOI, a description of how the FCOI relates to PHS-funded research, and key elements of the Institution's management plan.

- Requiring that before spending funds under a PHS-supported research project, an Institution is required to ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the three criteria as described in the regulations.
- Clarifying that PHS could require Institutions employing previously sanctioned Investigators to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.
- Clarifying that the PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interest and the Institution's review of, or response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a FCOI.
- Requiring training for Investigators prior to engaging in research related to any PHS-grant or contract, and at least every four years, and immediately when any of the following circumstances apply: (i) the Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators; (ii) an Investigator is new to an Institution; or (iii) an Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.
- Requiring institutions to perform and document a retrospective review in cases of non-compliance with the regulation. Institutions will report to the PHS-Awarding Component only in cases where bias is found and will provide a mitigation report to address the

impact of the bias on the research project and the actions the Institution has taken, or will take, to mitigate the bias.

The regulations require Investigators to disclose their SFIs[1], and those of the Investigator's spouse and dependent children, that reasonably appear to be related to the Investigator's institutional responsibilities. Institutions shall determine whether an Investigator's SFI is related

[1] (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

to PHS-funded research by determining whether the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. A FCOI exists when the institution, through its designated official(s), reasonably determines that a SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The institutional official(s) solicit and review disclosures of SFIs from each Investigator who is planning to participate in, or is participating in, the PHS-funded research. Investigator who are planning to participate in the PHS-funded research must disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than date of submission of the Institution's proposal for PHS-funded research. Investigators participating in PHS-funded research must submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of award and within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. Institutions shall take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report.

The Institution agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, or response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a FCOI. The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the

---

research institute that is affiliated with an Institution of higher education.

Institution's review of, or response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a FCOI. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with the regulations. On the basis of its review of records 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 the conflict of interest in accordance with the regulations. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.

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. 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 1994 NPRM (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 among 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 regulations at 42 CFR 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 that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, and contracts will be free from bias resulting from Investigator FCOIs. The regulations define "Investigator" as the project director or principal investigator and

any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. The regulations require that Institutions applying for, or receiving, PHS research funding by means of a grant, cooperative agreement, or contract maintain an up-to-date, written, enforced policy on FCOI that complies with the regulations, and make such policy available via a publicly accessible Web site[2]. Institutions must inform each Investigator of the Institution's policy on FCOI, the Investigator's responsibilities regarding disclosure of SFIs, and of the regulations. If an Institution maintains a policy on FCOI that includes standards that are more stringent than these regulations (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified FCOIs to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by the regulations.

We request approval for the revision 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(c)(1)(iii) and 94.4(c)(1)(iii)

[2] If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days.

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractor or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with the regulations by:
(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under these regulations.

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

(2) Providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators consistent with these regulations, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Section 50.604(k) and 94.4(k)

(k) Certify, in each application for funding or contract proposal to which these regulations apply, that the Institution:

(1) Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with the regulatory requirements including those pertaining to disclosure of SFIs;

(3) Shall manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with the regulations;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, or response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a FCOI; and

(5) Shall fully comply with the requirements of these regulations.

Section 50.605 and 94.5

(b) Reporting of FCOIs.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with these regulations. In cases in which the

Institution identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(2) For any SFI that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the FCOI and ensure that the Institution has implemented a management plan. Where such FCOI report involves a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also would be required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. If bias is found, the Institution will be required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component that addresses the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of these sections shall include sufficient information to enable the PHS Awarding Component to understand the nature and

extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not limited to the following:

(i) Project/Contract number;

(ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;

(iii) Name of the Investigator with the FCOI;

(iv) Name of the entity with which the Investigator has a conflicting interest;

(v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

(vi) Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the Institution's management plan, including:

(A) The role and principal duties of the conflicted Investigator in the research project;

(B) The conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

(4) For any FCOI previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

(5) In addition to the types of FCOIs as defined in these regulations that must be reported pursuant to this section, an Institution may require the reporting of other FCOIs in its policy in financial conflicts of interest, as the Institution deems appropriate.

Section 50.606(a) and 94.6(a):

a) If the failure of an Investigator to comply with an Institution's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Institution shall 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 PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

(b) The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, or response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a FCOI. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with these regulations. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI 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 the FCOI in accordance with these regulations. The PHS Awarding Component may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary for grants or cooperative agreements, or may determine that issuance of a Stop Work Order by the Contracting Officer or other enforcement action for a contract, is necessary until the matter is resolved.

Recordkeeping and/or Disclosure

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

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with these regulations by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

Recordkeeping
Section 50.604(i) and 94.4(i):

Each Institution shall maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a FCOI) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the

final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations for grants and cooperative agreements, and for at least three years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7 for contracts.

Disclosure

Section 50.604 and 94.4:

(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's SFIs (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research for grants and cooperative agreements and no later than date of submission of the Institution's proposal for PHS-funded research for contracts.

(2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of SFIs (e.g., any FCOI identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity interest).

(3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of SFIs within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Public Posting

Section 50.604(a) and 94.4(a)

Each Institution shall maintain an up-to-date, written, enforced policy on FCOI that complies with these regulations, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days.

Section 50.605(a)(5)(i)-(iv) and 94.5(a)(5)(i)-(iv)

Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any SFI disclosed to the Institution that meets the following three criteria:

(A) The SFI was disclosed and is still held by the senior/key personnel as defined by these regulations;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a FCOI.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-9,999; $10,000 - $19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional SFIs of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the PHS-funded research project, if the Institution determines that the SFI is related to the PHS-funded research and is a FCOI. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the

Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the SFIs of an individual subject to this paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

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

Since the last information collection submission in 2008, the regulations have been revised through the rulemaking process. Since the publication of the 1995 regulations, the growing complexity of biomedical and behavioral research; the increased interaction among Government, research Institutions, and the private sector in attaining common public health goals while meeting public expectations for research integrity; as well as increased public scrutiny, all raised questions as to whether a more rigorous approach to Investigator disclosure, institutional management of financial conflicts, and federal oversight is required. HHS decided to explore the need for revisions to the 1995 regulations by publishing an Advance Notice of Proposed Rulemaking on May 8, 2009 (74 FR 21610); a Notice of Proposed Rulemaking (75 FR 28688) on May 21, 2010; and a Notice (75 FR 42362) on July 21, 2010, extending the Notice of Proposed Rulemaking comment period. Changes to the regulations are discussed in greater detail in section A.1.

When an Institution seeks research funds for PHS grants, cooperative agreements, or contracts, the Institution certifies in the grant or cooperative agreement application or contract proposal that the Institution

(1) Has in effect at that Institution an up-to-date, written, and enforced administrative process that complies with this regulation to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with the regulatory's requirements including those pertaining to disclosure of SFIs;

(3) Shall manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with these regulations;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, or response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a FCOI; and

(5) Shall fully comply with the requirements of the regulations. Moreover, Institutions are required to certify compliance with all aspects of the regulation, including that Investigators are informed of the institutional policy, their disclosure responsibilities, and of the regulations. The disclosure of certain SFI information by Investigators to designated Institutional officials is necessary to provide a reasonable expectation that the design, conduct, and reporting of research

funded under PHS grants, cooperative agreements, and contracts will be free from bias resulting from Investigator FCOIs. The SFI information disclosed by the Investigators to the designated Institutional officials remains under the control of the Institutions.

As previously described, Institutions are required to report the existence of Investigator FCOIs to PHS Awarding Components and implement and report certain key elements of a management plan[3]. The Institution shall also provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project.

For grants and cooperative agreements, NIH requires that all FCOI reports and other related materials be submitted electronically through NIH's Electronic Research Administration (eRA) Commons FCOI Module. For NIH contracts, all FCOI reports and other related materials are to be submitted to the appropriate Director, Office of Acquisition, (http://oamp.od.nih.gov/AcquisitionOffices/chief_cos1.asp).

[3] 50.605(b)(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not limited to the following:

(i) Project number;

(ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;

(iii) Name of the Investigator with the financial conflict of interest;

(iv) Name of the entity with which the Investigator has a financial conflict of interest;

(v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

(vi) Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the Institution's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the research project;

(B) Conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

The FCOI Module will be revised to accommodate the collection of any additional information required by the Final Rule. Before the revised FCOI Module is implemented, NIH grant and cooperative agreement applicants and/or awardees will be able to submit additional information using the existing FCOI Module by uploading any additional required information as an attachment within the current system. The updated FCOI Module will accommodate the submission of the additional data elements provided in A.1.

Awarding PHS Components (at NIH, Institutes/Centers) may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review of, or response to, such disclosure, regardless of whether the disclosure resulted in an identified FCOI. In addition, Institutions are required to submit, or permit on site review of 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 paper forms. To reduce the recordkeeping and reporting burdens on the Institutions, NIH has developed an eRA Commons FCOI Module to allow grant and cooperative agreement Institutions to electronically submit, track, and manage required reports and other related materials. The eRA Commons is NIH's electronic interface with extramural grantee organizations, supporting the full life cycle of a grant. 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). A Privacy Impact Assessment (PIA) is in process.

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 continue to apply to Phase II Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Program applicants and recipients and other small entities. However, the regulations provide alternatives for those Institutions, many of which may be small businesses or other small entities, that do not have a presence on a publicly accessible Web site. Specifically, the regulations at 50.604(a) and 94.4(a) require that each Institution make available on a publicly accessible Web site its FCOI policy and information concerning any SFI disclosed to the Institution that meets the criteria found in 50.605(a)(5)(i) and 94.5(a)(5)(i). For both requirements, the regulations provide that if an Institution does not have a current presence on a publicly accessible Web site, the Institution may make the information available in writing within 5 business days of any request.

Additionally, as in the past, NIH/HHS will continue to engage in outreach activities to promote compliance with the regulations and will make resources available online, including guidance on policy development and a regulatory training module for Institutions and Investigators. Institutions should adapt these resources to incorporate information related to their specific policies and procedures, as needed.

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 on 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 Federal Register Notices were published on May 21, 2010, pages 28688-28712 (60 days) and an Extension Notice on July 21, 2010, pages 42362–42363 (30 days). The preamble of the final rule addresses the 136 unique comments received on the NPRM and the Extension Notice. As also provided in the preamble, the estimated annual cost of the amendments to the regulations is $23,236,238 and the estimated burden of implementing the revised regulations is 676,130 total burden hours. See comments under A12 below.

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 SFIs 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. The FCOI record system collects personally identifiable information and is subject to the Privacy Act in accordance with Privacy Act System of Record Notice # 09-25-0036.

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 FCOIs 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.

Today, approximately 3,000 Institutions that apply for PHS funding annually (excluding Phase I applicants and/or awardees under the Small Business Innovative Research [SBIR] program and Small Business Technology Transfer [STTR] program) are subject to the amended regulations. The amendment will affect the approximately 2,000 organizations (of all types,

excluding Phase I SBIR/STTRs) that are awarded PHS funding annually and, through the implementation of the regulations by the Institutions, to the estimated 38,000 Investigators participating in PHS-funded research that have SFIs. The cost of implementing the amended regulations is an allowable cost that may be eligible for reimbursement as a Facilities and Administrative cost on PHS supported grants, cooperative agreements and contracts. This could offset the cost burdens of implementation for the affected Institutions and through their implementation of the regulations, to the Investigators. Nonetheless, we are including a description of the estimated costs of the amendments to the regulations for general information. The estimate for the annual respondent burden for implementing the regulations is set forth in the following table.

Table 12a-Burden Table

Type of Respondents Based on Applicable Section of Regulation	**Number of Respondents**	**Frequency of Response**	**Average Burden per Response (in hrs.)**	**Total Burden Hours**
Reporting				
Initial Reports under 42 CFR 50.605 (b) (1) and (b)(3) or 45 CFR 94.5 (b) (1) and (b) (3) from awardee Institutions	950	1	2	1,900
Subsequent Reports under 42 CFR 50.605 (a)(3)(iii) and (b)(2) or 45 CFR 94.5 (a)(3)(iii) and (b)(2) from awardee Institutions	50 FCOI reports as in 42 CFR 50.605 (a)(3)(ii) and 45 CFR 94.5 (a)(3)(ii) 5 mitigation reports	1 1	2 2	100 10
Annual Report	950	1	1	950

under 42 CFR 50.605 (b)(4) or 45 CFR 94.5 (b) (4) from awardee Institutions				
Subsequent Reports under 42 CFR 50.606 (a) or 45 CFR 94.6 from awardee Institutions	20	1	10	200
Record Keeping				
Under 42 CFR 50.604 (i) or 45 CFR 94.4 (i) from awardee institutions	2,000	1	4	8,000
Disclosure				
Under 42 CFR 50.604(a) or 45 CFR 94.4 for Investigators	3,000	1	81	243,000
Under 42 CFR 50.604(b) or 45 CFR 94.4 (e)(1) for Investigators	38,000	1	30/60	19,000
Under 42 CFR 50.604(b) or 45 CFR 94.4 (e)(1) for Institutions	2,000	1	6	12,000
Under 42 CFR 50.604 (c)(1) or 45 CFR 94.4 (c) (1) from subrecipients	500	1	1	500
Under 42 CFR 50.604(d) or 45 CFR 94.4 for Institutions	3,000[4]	1	1	3,000
Under 42 CFR 50.604 (e)(1) or 45 CFR 94.4 (e) (1) for Investigators	38,000	1	4	152,000

[4] Assuming that 3,000 Institutions solicit disclosures on an annual basis by sending a notification to all Investigators.

Under 42 CFR 50.604 (e)(2) or 45 CFR 94.4 (e)(2) for Investigators	38,000	1	1	38,000
Under 42 CFR 50.604 (e)(3) or 45 CFR 94.4 (e)(3) for Investigators	950	1	30/60	475
Under 42 CFR 50.604(f) or 45 CFR 94.4 (f)for institutions	2,000	1	1	2,000
Under 42 CFR 50.605 (a)(1) or 45 CFR 94.5 (a)(1) for Institutions	2,000 [5]	1	82	164,000
Under 42 CFR 50.605 (a)(3) or 45 CFR 94.5 (a)(3) for Institutions	500[6]	1	3	1,500
Under 42 CFR 50.605 (a)(3)(i) or 45 CFR 94.5 (a)(3)(i)	50[7]	1	80	4,000
Under 42 CFR 50.605 (a)(3)(ii) or 45 CFR 94.5 (a)(3)(ii)	50[8]	1	80	4,000
Under 42 CFR	50	1	1	50

[5] Although an estimated 950 reports of Conflict of Interest are expected annually, the 2,000 responding Institutions must review all financial disclosures associated with PHS-funded awards to determine whether any conflicts of interest exist. Thus, the review burden of 76,000 hours is based upon estimates that it will take on the average 2 hours for an institutional official(s) to review each of 38,000 financial disclosures associated with PHS funded awards. The burden for developing a management plan for identified FCOI is estimated at 80 hours x 950 cases = 76,000 hours.

[6] Assuming that this is a rare occurrence based on prior experience.

[7] Assuming only a fraction of the newly identified SFIs will constitute FCOI.

[8] Assuming only a fraction of the newly identified SFIs will constitute FCOI.

50.605 (a)(3)(iii) or 45 CFR 94.5 (a)(3)(iii)				
Under 42 CFR 50.605 (a)(4) or 45 CFR 94.5 (a) (4)	950	1	12	11400
Public Website Posting under 42 CFR 50.605 (a) (5) or 45 CFR 94.5 (a)(5) from awardee Institutions	2,000	1	5	10,000
Under 42 CFR 50.606 (c) or 45 CFR 94.6 (c)	50[9]	3[10]	0.3	45

Total Burden Hours: 676,130

Table 12b-Burden Table

Type of Respondents Based on Applicable Section of Regulation	**Total Burden Hours**	**Wage Rate per Hour**	**Total Burden Cost**
Reporting			
Initial Reports under 42 CFR 50.605 (b) (1) and (b)(3) or 45 CFR 94.5 (b) (1) and (b) (3) from Institutions	1,900	$35	$66,500
Subsequent Reports under 42 CFR 50.605	100	$35	$3,500

[9] Number based on 50.605/94.5 (a)(3)(i) - of those only a fraction will relate to a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, but we are calculating the maximum estimated burden.

[10] Assuming an average of 3 publications annually.

(a)(3)(iii) and (b)(2) or 45 CFR 94.5 (a)(3)(iii) and (b)(2) from Institutions	10		$350
Annual Report under 42 CFR 50.605 (b)(4) or 45 CFR 94.5 (b)(4) from Institutions	950	$35	$33,250
Subsequent Reports under 42 CFR 50.606 (a) or 45 CFR 94.6 from Institutions	200	$35	$7,000
Record Keeping			
Under 42 CFR 50.604 (i) or 45 CFR 94.4 (i) from awardee institutions	8,000	$35	$280,000
Disclosure			
Under 42 CFR 50.604(a) or 45 CFR 94.4 for Investigators	243,000	$35	$8,505,000
Under 42 CFR 50.604(b) or 45 CFR 94.4 (b) for Investigators	19,000	$35	$665,000
Under 42 CFR 50.604(b) or 45 CFR 94.4 (b) for Institutions	12,000	$35	$420,000
Under 42 CFR 50.604 (c)(1) or 45 CFR	500	$35	$17,500

94.4 (c)(1) from subrecipients			
Under 42 CFR 50.604(d) or 45 CFR 94.4 for Institutions	3,000	$35	$105,000
Under 42 CFR 50.604 (e)(1) or 45 CFR 94.4 (e)(1) from Investigators	152,000	$35	$5,320,000
Under 42 CFR 50.604 (e)(2) or 45 CFR 94.4 (e)(2) from Investigators	38,000	$35	$1,330,000
Under 42 CFR 50.604 (e)(3) or 45 CFR 94.4 (e)(3) from Investigators	475	$35	$8,313
Under 42 CFR 50.604(f) or 45 CFR 94.4 (f)for institutions	2,000	$35	$70,000
Under 42 CFR 50.605 (a)(1) or 45 CFR 94.5 (a)(1) for Institutions	164,000	$35	$5,740,000[11]
Under 42 CFR 50.605 (a) (3) or 45 CFR 94.5 (a)(3) for Institutions	1500	$35	$52,500
Under 42 CFR 50.605 (a)(3)	4000	$35	$140,000

[11] $70 for review and $2,800 for developing management plan
Total: $2,870 each institution/$2,660,000 for review of all disclosures plus $2,660,000 for developing management plans of those identified as FCOI for 2,000 institutions

(i) or 45 CFR 94.5 (a)(3)(i)			
Under 42 CFR 50.605 (a)(3) (ii) or 45 CFR 94.5 (a)(3)(ii)	4000	$35	$140,000
Under 42 CFR 50.605 (a)(3) (iii) or 45 CFR 94.5 (a)(3)(iii)	50	$35	$1,750
Under 42 CFR 50.605 (a)(4) or 45 CFR 94.5 (a)(4)	11400	$35	$399,000
Public Website Posting under 42 CFR 50.605 (a) (5) or 45 CFR 94.5 (a) (5) from awardee Institutions	10,000	$35	$350,000
Under 42 CFR 50.606 (c) or 45 CFR 94.6 (c)	45	$35	$1,575
Total			$ 23,656,238

Total annual cost: $23,656,238

13. <u>Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers</u>

Operating Costs, and/or Maintenance Costs per response are $13,261.50.

14. <u>Annualized Cost to the Federal Government</u>

The estimated annual cost to the Government of these regulations includes the maintenance of established electronic systems to receive and manage reports and information received from

Institutions (eRA Commons FCOI Module and internal Web-based electronic system) and the review and analysis of reports and other information from Institutions: 1) of identified FCOIs submitted prior to the Institution's expenditure of any funds under a PHS-funded research project; 2) of FCOIs identified after the initial report submitted within sixty days of the identification; 3) annual reports for Investigator FCOIs previously reported, 4) updates of FCOI reports; 5) notifications 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, which includes corrective action taken or to be taken; 6) Institutional retrospective reviews, when required, to determine whether any PHS-funded research, or portion thereof, was biased in the design, conduct, or reporting; 7) mitigation reports in cases where bias is found as a result of a retrospective review; 8) other reports required by the Institution; and 9) in response to the Government's request for additional information.

15. In this revision of this Information Collection Request the cost to the Government has been estimated based upon the receipt of approximately950 reports on an annual basis. In this revision, it is anticipated that in addition to the increase in the type and number of reports and other documentation received, the Government involvement will increase overall and may vary considerably from case to case. On average, each case would require 41 hours spent on review, correspondence, and record keeping. Estimating 40 hours effort per case by senior officials at $55.00/hour and 1 hour effort per case by support staff at $12.00/hour, the annual cost to the Government is $2,101,400. **Explanation for Program Changes or Adjustments**

The estimated total annual burden hours has been increased from 220,080 to 676,130. This upward adjustment is due to the changes to the regulations. See coments under A12.

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.

Project Time Schedule and Compliance Dates:

In the interim of the following time periods, Institutions will continue to follow their existing Financial Conflict of Interest (FCOI) policies and report Investigator FCOIs to the Public Health Service (PHS) Awarding Component as required in the 1995 regulations.

Activity	Time Schedule
Revise FCOI policy or develop a new policy.	180 calendar days after publication of the final rule
• Post the institutional FCOI policy on a publicly accessible Web site or make information available if requested. • Report identified FCOIs and all related information. • Develop and initiate Investigator training.	60 calendar days after implementation of the revised FCOI policy or 240 days after publication of the final rule, whichever is earlier
Make information on FCOIs of senior/key personnel publicly accessible via a publicly accessible Web site or by making information available upon written request.	270 calendar days after publication of the final rule

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

While there are no paper 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. <u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>

There are no exceptions.

B. Statistical Methods

This collection of information does not employ statistical methods.