SUPPORTING STATEMENT A
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 (NIH/OD)
45 CFR Part 94
OMB No. 0925-0417 2/28/2015

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A. Justification

The regulations provided in **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) are necessary to promote objectivity of the design, conduct, and reporting of research funded by the Public Health Service (PHS). The NIH failed to respond timely to the expiration of this submission and the submission of a reinstatement with change is due to NIH's focused efforts on the consideration of the analysis of comments received during the Notice of Proposed Rule Making (NPRM) in development of the Final Rule and its implementation to the research community to ensure their understanding and compliance with the different requirements. The disclosure of Investigators' Significant Financial Interests (SFIs) to the awardee Institution's designated official(s) for a determination of a financial conflict of interests adds transparency and enhances regulatory compliance and effective institutional oversight and management of identified Investigator financial conflicts of interests. The collection of financial conflict of interest information enhances the Department of Health and Human Services' (HHS) compliance oversight by allowing HHS to review key elements of the Institution's management plan with respect to the identified financial conflict of interest. These requirements work together to preserve the public's trust that the research supported by the PHS is conducted without bias and with the highest scientific and ethical standards.

A.1. Circumstances Making the Collection of Information Necessary

This request is for Office of Management and Budget (OMB) approval of a reinstatement without change of a currently approved collection resulting from the publication of the 2011 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). HHS published the final rule on August 25, 2011.

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 financial conflicts of interest. 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 financial conflict of interest that complies with the regulations, and make such policy available via a publicly accessible Web site.[1]. Institutions must inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of SFIs, and of the regulations. If an Institution maintains a policy on financial conflicts of interest 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 financial conflict of interest (FCOI) reports regarding identified financial conflicts of interest 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 reinstatement without change the collection and recordkeeping requirements set forth in the regulation 42 CFR Part 50, Subpart F and 45 CFR Part 94.

Reporting

[11] 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 50.604(c)(1)(iii) and 94.4(c)(1)(iii)

(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 financial conflict of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests 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 financial conflicts of interests of all subrecipient Investigators consistent with these regulations, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified financial conflict of interest.

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 financial conflicts of interest 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 significant financial interests;

(3) Shall manage financial conflicts of interest 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 financial conflict of interest; and

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

Section 50.605(b)(1)-(5) and 94.5(b)(1)-(5)

(b) Reporting of financial conflicts of interest.

(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 significant financial interest 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 a financial conflict of interest 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 significant financial interest 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 financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with the regulations. Pursuant to paragraph 42 CFR 50.604(a)(3)(ii) and 45

CFR 94.5(a)(3)(ii) where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (*e.g.*, was not timely reviewed or reported by a subrecipient), the Institution also is 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 financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of these sections, if bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

(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 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.

(4) For any financial conflict of interest 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 financial conflicts of interest as defined in these regulations that must be reported pursuant to this section, an Institution may require the reporting of other

financial conflicts of interest in its policy on 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 financial conflict of interest policy or a financial conflict of interest 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.

Section 50.506(b) and 94.6(b)

(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 financial conflict of interest. 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 financial conflict of interest in accordance with these regulations. The PHS Awarding Component may determine that imposition of specific award

conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371 (for grants and cooperative agreements) or issuance of a Stop Work Order by the Contracting Officer or other enforcement action (for contracts) 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 financial conflict of interest 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):

(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 financial conflict of interest) 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 75.361 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(e)(1)-(3) and 94.4(e)(1)-(3):

(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 significant financial interests (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 significant financial interests 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 significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interests (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 significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Public Posting

Section 50.604(a) and 94.4(a)

(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)

(5)(i) 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 significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest 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 significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant 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.

(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 significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. 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 significant financial interests of an individual subject to 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.

A.2. Purpose and Use of the Information Collection

As previously described, Institutions are required to report the existence of Investigator financial conflict of interest to PHS Awarding Components and implement and report certain key elements of a management plan[2]. The Institution shall also provide to the PHS Awarding Component an annual FCOI

[2] 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;

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 collection and recordkeeping requirements allow the agency to provide oversight of Investigator financial conflicts of interest for promoting objectivity in PHS-funded research.

For grants and cooperative agreements, NIH and the Agency for Healthcare Research and Quality 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 NIH Contracting Officer identified on the contract.

The external FCOI Module was enhanced several years ago to implement a system-generated email reminder to the FCOI signing official to remind recipient staff when Annual reports are due. FCOI training on reporting requirements for both the external recipient community and NIH staff has been conducted. There does not appear to be any major problems or complications with the submission, receipt and review of FCOI reports.

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.

(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.

On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular Financial 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 Financial Conflict of Interest in accordance with the regulation, the PHS Awarding Component may, consistent with the grant regulations determine that imposition of specific award conditions under 45 CFR 75.207, or suspension of funding or other enforcement action under 45 CFR 75.371, is necessary until the matter is resolved. For contracts, the PHS Awarding Component may determine that issuance of a Stop Work Order by the Contracting Officer or other enforcement action is necessary until the matter is resolved.

A.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 developed and enhanced an eRA Commons FCOI Module to allow grant and cooperative agreement Institutions to electronically submit, track, and manage required FCOI reports and other related materials. The eRA Commons is NIH's electronic interface with extramural recipient organizations, supporting the full life cycle of a grant. 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 PIA has been completed for the system that is used for this clearance.

A.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.

A.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 significant financial interest 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 five business days of any request.

Additionally, as in the past, NIH/HHS continues to engage in outreach activities to promote compliance with the regulations. NIH has made many resources available online, including guidance on policy development, frequently asked questions, 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.

A.6. Consequences of Collecting the Information Less Frequently

The information is collected after the Institution identifies a financial conflict of interest consistent with the regulatory requirements. Once an initial FCOI report is submitted, an annual FCOI report is submitted each year throughout the competitive segment or until the Institution reports that the FCOI no longer exists. Collecting the information less frequently may cause the Agency to have information that is not current.

A.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.

A.8.1. Comments in Response to the Federal Register Notice

The 60-day Federal Register Notice was published on 3/16/18, Volume 83, No. 52 on page 11763. In compliance with 5 CFR §1320.8 (d). One comment was received as provided in Attachment 1. The comment was considered but does not require action relative to the collection of information.

A.8.2. Efforts to Consult Outside the Agency

Consultation outside the Agency did not occur.

A.9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

A.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: 09-25-0036, titled, Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH.

A.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. 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.

A.12.1. Estimates of Hour Burden including Annualized Hourly Costs

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 2011 revised regulation amendment affects 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 significant financial interests. 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 complying with the regulations is set forth in the following table. The numbers for the initial and annual reports is based on current estimated data.

Table 12-1 Estimated Annualized Burden Hours

Type of Respondents Based on Applicable Section of Regulation	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden per Response (in hrs.)**	**Total Annual 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	992	1	2	1,984

Institutions				
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 under 42 CFR 50.605 (b)(4) or 45 CFR 94.5 (b)(4) from awardee Institutions	2,031	1	1	2,031
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	3,000[3]	1	1	3,000

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

50.604(d) or 45 CFR 94.4 for Institutions				
Under 42 CFR 50.604 (e)(1) or 45 CFR 94.4 (e)(1) for Investigators	38,000	1	4	152,000
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	992	1	30/60	496
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 [4]	1	82	164,000
Under 42 CFR 50.605 (a)(3) or 45 CFR 94.5 (a)(3) for Institutions	500[5]	1	3	1,500
Under 42 CFR 50.605 (a)(3)(i) or 45 CFR 94.5 (a)(3)(i)	50[6]	1	80	4,000
Under 42 CFR 50.605 (a)(3)(ii) or	50[7]	1	80	4,000

[4] Although an estimated 992 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 992 cases = 79,360 hours.

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

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

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

45 CFR 94.5 (a)(3)(ii)				
Under 42 CFR 50.605 (a)(3)(iii) or 45 CFR 94.5 (a)(3)(iii)	50	1	1	50
Under 42 CFR 50.605 (a)(4) or 45 CFR 94.5 (a)(4)	992	1	12	11,904
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[8]	3[9]	18/60	45
TOTAL	136,282	136,282		677,820

Table 12-2 Annualized Cost to Respondents

Type of Respondents Based on Applicable Section of Regulation	**Total Annual Burden Hours**	**Hourly Respondent Wage Rate**	**Respondent 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	1,984	$44[10] $87,296	
Subsequent Reports under	100	$44	$4,400

[8] 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.

[9] Assuming an average of 3 publications annually.

[10] United States Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook. Average of University administrators or Postsecondary Education Administrators obtained from https://www.bls.gov/ooh/management/postsecondary-education-administrators.htm $44.41 per hour

42 CFR 50.605 (a)(3)(iii) and (b)(2) or 45 CFR 94.5 (a)(3)(iii) and (b)(2) from Institutions	10		$440
Annual Report under 42 CFR 50.605 (b)(4) or 45 CFR 94.5 (b)(4) from Institutions	2,031	$44	$89,364
Subsequent Reports under 42 CFR 50.606 (a) or 45 CFR 94.6 from Institutions	200	$44	$8,800
Record Keeping			
Under 42 CFR 50.604 (i) or 45 CFR 94.4 (i) from awardee institutions	8,000	$44	$352,000
Disclosure			
Under 42 CFR 50.604(a) or 45 CFR 94.4 for Investigators	243,000	$44	$10,692,000
Under 42 CFR 50.604(b) or 45 CFR 94.4 (b) for Investigators	19,000	$44	$836,000
Under 42 CFR 50.604(b) or 45 CFR 94.4 (b) for Institutions	12,000	$44	$528,000
Under 42 CFR 50.604 (c)(1) or 45 CFR 94.4 (c)(1) from subrecipients	500	$44	$22,000
Under 42 CFR 50.604(d) or 45 CFR 94.4 for Institutions	3,000	$44	$132,000
Under 42 CFR	152,000	$44	$6,688,000

50.604 (e)(1) or 45 CFR 94.4 (e)(1) from Investigators			
Under 42 CFR 50.604 (e)(2) or 45 CFR 94.4 (e)(2) from Investigators	38,000	$44	$1,672,000
Under 42 CFR 50.604 (e)(3) or 45 CFR 94.4 (e)(3) from Investigators	475	$44	$20,900
Under 42 CFR 50.604(f) or 45 CFR 94.4 (f)for institutions	2,000	$44	$88,000
Under 42 CFR 50.605 (a)(1) or 45 CFR 94.5 (a)(1) for Institutions	164,000	$44	$7,216,000
Under 42 CFR 50.605 (a) (3) or 45 CFR 94.5 (a)(3) for Institutions	1,500	$44	$66,000
Under 42 CFR 50.605 (a)(3)(i) or 45 CFR 94.5 (a)(3)(i)	4,000	$44	$176,000
Under 42 CFR 50.605 (a)(3)(ii) or 45 CFR 94.5 (a)(3)(ii)	4,000	$44	$176,000
Under 42 CFR 50.605 (a)(3)(iii) or 45 CFR 94.5 (a)(3)(iii)	50	$44	$2,200
Under 42 CFR 50.605 (a)(4) or 45 CFR 94.5 (a)(4)	11,904	$44	$523,776
Public Website Posting under 42 CFR 50.605	10,000	$44	$440,000

(a) (5) or 45 CFR 94.5 (a)(5) from awardee Institutions			
Under 42 CFR 50.606 (c) or 45 CFR 94.6 (c)	45	$44	$1,980
Total			$ 29,823,156

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

Other annual costs to respondents or record keepers are associated with customary and usual business or practices of organizations that submit financial conflict of interest reports. There are no additional costs to respondents.

A.14. Annualized Cost to the Federal Government

The estimated annual cost to the Government is approximately $14,897. This information is calculated based on the NIH Grants Compliance Analyst's salary and percentage of effort devoted to preparing this submission. These expenses would not have incurred without this collection of information.

Table A.14 Total Annual Cost to the Federal Government

Cost Descriptions	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Federal Grants Compliance Analyst	14/10	$148,967	10%		$14,897
Contractor Cost					

Travel					
Other Cost					
Total					$14,897

**https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf

A.15. Explanation for Program Changes or Adjustments

The adjustment of 992 for the initial reports represents an increase in respondents (those reporting an initial FCOI) vs. additional requirements. The initial table published was an estimate and with this reinstatement with change, we had some data on actual numbers. The increase in burden is only an increase in the actual reported initial FCOI reports than was originally estimated.

A.16. Plans for Tabulation and Publication and Project Time Schedule

There is no tabulation, publication, or project time schedule associated with FCOI reporting.

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

The OMB expiration date will be displayed on the appropriate data collection instruments.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions.