



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB review; 30-day comment request; Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought and Responsible Prospective Contractors (Office of the Director)**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Diane Dean, Director, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, Office of Extramural Research, National Institutes of Health, 6705 Rockledge Drive, Room 3525, Bethesda, MD 20892, or call

non-toll-free number (301) 435-0930 or E-mail your request, including your address to: deand@od31em1.od.nih.gov.

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the Federal Register on March 16, 2018, (FR 83 pages 11763-11765) and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: 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, 0925-0417, expiration date 2/28/2015, REINSTATEMENT WITHOUT CHANGE, Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This request is for Office of Management and Budget (OMB) approval of a Reinstatement Without Change 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). The purpose of these regulations is to promote objectivity in research by requiring institutions to establish standards 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).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 677,820.

Estimated Annualized Burden Hours

<b>Type of Respondents Based on Applicable Section of Regulation</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden per Response (in hrs.)</b>	<b>Total Annual Burden Hours</b>
<b>Reporting</b>				
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	992	1	2	1,984
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)	1	2	100
	5 mitigation reports	1	2	10
Annual Report under 42 CFR	2,031	1	1	2,031

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
<b>Record Keeping</b>				
Under 42 CFR 50.604 (i) or 45 CFR 94.4 (i) from awardee institutions	2,000	1	4	8,000
<b>Disclosure</b>				
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 <sup>1</sup>	1	1	3,000
Under 42 CFR 50.604 (e)(1) or	38,000	1	4	152,000

<sup>1</sup> Assuming that 3,000 Institutions solicit disclosures on an annual basis by sending a notification to all Investigators.

45 CFR 94.4 (e)(1) for 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	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 <sup>2</sup>	1	82	164,000
Under 42 CFR 50.605 (a)(3) or 45 CFR 94.5 (a)(3) for Institutions	500 <sup>3</sup>	1	3	1,500
Under 42 CFR 50.605 (a)(3)(i) or 45 CFR 94.5 (a)(3)(i)	50 <sup>4</sup>	1	80	4,000
Under 42 CFR 50.605 (a)(3)(ii)	50 <sup>5</sup>	1	80	4,000

<sup>2</sup> 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.

<sup>3</sup> Assuming that this is a rare occurrence based on prior experience.

<sup>4</sup> Assuming only a fraction of the newly identified SFIs will constitute FCOI.

<sup>5</sup> Assuming only a fraction of the newly identified SFIs will constitute FCOI.

or 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 <sup>6</sup>	3 <sup>7</sup>	18/60	45
<b>Total</b>	136,282	136,382		677,820

Dated: August 30,2018.

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Lawrence A. Tabak,

Deputy Director,

National Institutes of Health.

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<sup>6</sup> 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.

<sup>7</sup> Assuming an average of 3 publications annually.