



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-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 Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), Office of the Director, (OD)

AGENCY: National Institutes of Health, (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health, Office of Policy and Extramural Research Administration (OPERA), Office of Extramural Research (OER), Office of the Director (OD) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Kathy Hancock, Asst. Grants Compliance Officer, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland, 20892 or call non-toll-free number 301.435.0949 or E-mail your request to FCOICompliance@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought 45 CFR Part 50

Subpart F and Responsible Prospective Contractors 45 CFR Part 94, 0925-0417, --  
 REINSTATEMENT WITHOUT CHANGE Office of Policy and Extramural Research  
 Administration (OPERA) Office of Extramural Research (OER), Office of the Director  
 (OD), 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 677,295.

Estimated Annualized Burden Hours

Type of Respondents based on Applicable Section of Regulation	Number of Respondents	Frequency of Responses	Average Time Per Response (in hours)	Total Annual Burden Hour
<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
Annual Report under 42 CFR 50.605 (b)(4) or 45 CFR 94.5 (b)(4) from awardee Institutions.....	5 mitigation reports	1	2	10
Subsequent Reports under 42 CFR 50.606 (a) or 45 CFR 94.6 from awardee Institutions.....	2031	1	1	2031
	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>4</sup>	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
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

<sup>4</sup> Assuming that 3,000 Institutions solicit disclosures on an annual basis by sending a notification to all Investigators.

Under 42 CFR 50.605 (a)(1) or 45 CFR 94.5 (a)(1) for Institutions.....	2,000 <sup>5</sup>	1	82	164,000
Under 42 CFR 50.605 (a) (3) or 45 CFR 94.5 (a)(3) for Institutions.....	500 <sup>6</sup>	1	3	1,500
Under 42 CFR 50.605 (a)(3)(i) or 45 CFR 94.5 (a)(3)(i) .....	50 <sup>7</sup>	1	80	4,000
Under 42 CFR 50.605 (a)(3)(ii) or 45 CFR 94.5 (a)(3)(ii) .....	50 <sup>8</sup>	1	80	4,000
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) .....	950	1	12	11,400
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>9</sup>	3 <sup>10</sup>	18/60	45
<b>Total</b>	<b>136,143</b>	<b>136,243</b>		<b>677,295</b>

<sup>5</sup> 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.

<sup>6</sup> Assuming that this is a rare occurrence based on prior experience.

<sup>7</sup> Assuming only a fraction of the newly identified SFIs will constitute FCOI.

<sup>8</sup> Assuming only a fraction of the newly identified SFIs will constitute FCOI.

<sup>9</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>10</sup> Assuming an average of 3 publications annually.

Dated: March 10, 2018.

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Lawrence A. Tabak,

Deputy Director,

National Institutes of Health.

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