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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Promoting Objectivity in Research 42 CFR Part 50 Subpart F and Responsible Prospective Contractors 45 CFR Part 94 (NIH/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) will publish periodic summaries of proposed 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: Brian E. Sass-Hurst, Acting Director, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, National Institutes of Health, 6705 Rockledge Drive, Suite 800, or call non-toll-free number (301) 827-7581 or E-mail your request, including your address to Brian.Sass-Hurst@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: Promoting Objectivity in Research 42 CFR Part 50 Subpart F and Responsible Prospective Contractors 45 CFR Part 94, 0925-0417, expiration date 06/30/2025, EXTENSION, 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 an Extension of a currently approved collection resulting from regulations regarding Promoting Objectivity in Research (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 Public Health Service (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 680,473.

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 Institutions	1,128	1	2	2,256
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	2,712	1	1	2,712
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[1]	1	1	3,000

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	1,128	1	30/60	564
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 [2]	1	82	164,000
Under 42 CFR 50.605 (a)(3) or 45 CFR 94.5 (a)(3) for Institutions	500[3]	1	3	1,500
Under 42 CFR 50.605 (a)(3)(i) or 45 CFR 94.5 (a)(3)(i)	50[4]	1	80	4,000
Under 42 CFR 50.605 (a)(3)(ii) or 45 CFR 94.5 (a)(3)(ii)	50[5]	1	80	4,000
Under 42 CFR 50.605 (a)(3)(iii) or 45 CFR 94.5 (a)(3)(iii)	50	1	1	50

[1] Assuming that 3000 institutions solicit disclosures on an annual basis to all Investigators

[2] Although an estimated 1,128 reports of Financial 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 financial 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 1,128 cases = 90,240 hours.

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

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

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

[6] 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.

Under 42 CFR 50.605 (a)(4) or 45 CFR 94.5 (a)(4)	1,128	1	12	13,536
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[6]	3[76]	18/60	45
TOTAL	137,371	137,371		680,473

Dated: July 3, 2025.

Jon Lorsch,

Acting NIH Deputy Director for Extramural Research,

National Institutes of Health.

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[7] Assuming an average of 3 publications annually.