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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day Comment Request; The Impact and Costs of Promoting Objectivity in Research 42 CFR Part 50 Subpart F and Responsible Prospective Contractors 45 CFR Part 94 (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 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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: Mr. Romeo K. Tengey, Director, Division of Compliance of Foreign Interference Research Misconduct, Harassment, and Intellectual, Office of Policy for Extramural Research Administration, Office of Extramural Research, National Institutes of Health, 6705 Rockledge Drive, Suite 800, Bethesda, MD 20892, or call non-toll-free number (301) 402-0892 or E-mail your request, including your address to: *Tengeyr@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously

published in the *Federal Register* on July 10, 2025 (FR 90-page 30649) and allowed 60 days for public comment. No comments were 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: Promoting Objectivity in Research 42 CFR part 50 Subpart F and Responsible Prospective Contractors 45 CFR part 94, 0925-0417, expiration date 6/30/2025, Reinstatement With 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 With Change of a currently approved collection resulting from the development of revised regulations regarding the 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). NIH is implementing a change or enhancement in the FCOI reporting requirement within the eRA Commons FCOI Module to require the grant and cooperative agreement respondent to identify foreign FCOIs and provide the type of foreign entity and the name of the foreign country. This enhanced requirement is insignificant on the part of respondents.

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(a) 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(a) for Investigators	3,000	1	81	243,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Investigators	38,000	1	30/60	19,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Institutions	2,000	1	6	12,000
Under 42 CFR 50.604(c)(1) or 45	500	1	1	500

CFR 94.4(c)(1) from subrecipients				
Under 42 CFR 50.604(d) or 45 CFR 94.4(d) for Institutions	3,000[1]	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	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
Under 42 CFR 50.605(a)(4) or 45	1,128	1	12	13,536

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

CFR 94.5(a)(4)				
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[7]	18/60	45
Total	137,371	137,471		680,473

The Deputy Director for Extramural Research, Jon Lorsch, having reviewed and approved this document, authorizes Alycia Booth, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 17, 2026.

Alycia Booth,

Federal Register Liaison,

National Institutes of Health.

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[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.

[7] Assuming an average of 3 publications annually.