

Dated: April 4, 2021.

**Lawrence A. Tabak,**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; 60-Day Comment Request; Post-Award Reporting Requirements Including Research Performance Progress Report Collection (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 (NIH) 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: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301–435–0941 or Email your request, including your address to [ProjectClearanceBranch@mail.nih.gov](mailto:ProjectClearanceBranch@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

on 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:* Public Health Service (PHS) Post-award Reporting Requirements Including Research Performance Progress Report (RPPR) Collection, Revision, OMB 0925–0002, Expiration Date 2/28/2023, Office of the Director (OD), National Institutes of Health (NIH).

*Need and Use of Information Collection:* This collection is being revised because starting in January 2022, NIH will require will applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number. Also, the application forms will be updated to align with the [Grants.gov](https://www.grants.gov) updated Country and State lists. NIH also anticipates adding an optional field to the end of our forms and applications to get a more accurate assessment of the time it takes our applicants to complete the various forms and applications. The RPPR is required to be used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR required the maintenance of dual reporting processes for a period of time. Continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), exists for a small group of grantees. This collection also includes

other PHS post-award reporting requirements: PHS 416–7 NRSA Termination Notice, PHS 2271 Statement of Appointment, 6031–1 NRSA Annual Payback Activities Certification, HHS 568 Final Invention Statement and Certification, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. The PHS 416–7, 2271, and 6031–1 is used by NRSA recipients to activate, terminate, and provide for payback of a NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another. Pre-award reporting requirements are simultaneously consolidated under 0925–0001 and the changes to the collection here are related. Clinical trials are complex and challenging research activities. Oversight systems and tools are critical for NIH to ensure participant safety, data integrity, and accountability of the use of public funds. NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information in the PHS applications and pre-award reporting requirements as well as continued monitoring and update during the post-award reporting requirements will facilitate NIH's oversight of clinical trials. In addition, some of the data reported in the RPPR will ultimately be accessible to investigators to update certain sections of forms when registering or reporting their trials with [ClinicalTrials.gov](https://clinicaltrials.gov).

*Frequency of response:* Applicants may submit applications for published receipt dates. For NRSA awards, fellowships are activated, and trainees appointed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 535,579.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
<b>REPORTING</b>				
PHS 416–7 .....	12,580	1	30/60	6,290

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
PHS 6031–1 .....	1,778	1	20/60	593
PHS 568 .....	11,180	1	5/60	932
iEdison .....	5,697	1	15/60	1,424
PHS 2271 .....	22,035	1	15/60	5,509
PHS 2590 .....	243	1	18	4,374
RPPR—Core Data .....	32,098	1	8	256,784
Biosketch (Part of RPPR) .....	2,544	1	2	5,088
Data Tables (Part of RPPR) .....	758	1	4	3,032
Trainee Diversity Report (Part of RPPR) .....	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report) .....	6,420	1	4	25,680
Publication Reporting .....	97,023	3	5/60	24,256
Final RPPR—Core Data .....	18,000	1	10	180,000
Data Tables (Part of Final RPPR) .....	758	1	4	3,032
Trainee Diversity Report (Part of Final RPPR) .....	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report) .....	3,600	1	4	14,400
PHS 374 .....	479	1	30/60	240
Final Progress Report .....	2,000	1	1	2,000
SBIR/STTR Phase II Final Progress Report .....	1,330	1	1	1,330
Reporting Burden Total .....				535,204
<b>RECORDKEEPING</b>				
SBIR/STTR Life Cycle Certification .....	1,500	1	15/60	375
Grand Total .....	220,983	415,029		535,579

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**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****[Docket No. USCG–2021–0190]****Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0018****AGENCY:** Coast Guard, DHS.**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0018, Official Logbook; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to

OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before June 11, 2021.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2021–0190] to the Coast Guard using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public participation and request for comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:****Public Participation and Request for Comments**

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection’s purpose, the Collection’s likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.