[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Post-Award Reporting Requirements Including Research Performance Progress Report Collection (OD/OPERA)

AGENCY: National Institutes of Health.

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. This proposed information collection was previously published in the Federal Register on November 2, 2016, Volume 81, No.212, pages 76371-76372 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

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 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: contact Ms. Mikia P. Currie, Project Clearance Branch, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892-7974, or call non-toll-free number (301) 435-0941, or E-mail your request, including your address to: trialsinfo@od.nih.gov.

SUPPLEMENTARY INFORMATION: The Office of the Director, National Institutes of Health (NIH), 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 (PRA) of 1995, the 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: Public Health Service (PHS) Post-award Reporting Requirements.

Revision, OMB 0925–0002, Expiration Date 10/31/2018. Form numbers: PHS 2590,

PHS 416-7, PHS 2271, PHS 3734, PHS 6031-1, and HHS 568. This collection represents a consolidation of post-award reporting requirements under the PRA, including the Research Performance Progress Report (RPPR). This collection includes the proposed additional reporting requirements for clinical trials.

Need and Use of Information Collection: The RPPR is now required to be used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality 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, Final Progress Report instructions, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. The PHS 416–7, 2271, and 6031–1 are 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. Using 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. The Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) Life Cycle Certifications are completed by small business

grantees once certain milestones are reached during the project period. 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 the NIH to ensure participant safety, data integrity, and accountability of the use of public funds. The 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 the 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 519,408.

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
REPORTING				
PHS 416-7	12,580	1	30/60	6,290
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	8,085
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 Final RPPR, includes inclusion/enrollment)	3,600	1	4	14,400
PHS 3734	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				499,033
RECORDKEEPING				
SBIR/STTR Life Cycle Certification	1,500	1	15/60	375
Grand Total				**519,408**

Dated: February 1, 2017

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Lawrence A. Tabak, D.D.S., Ph.D.

Deputy Director

National Institutes of Health

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