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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)

SUMMARY: Under the provisions of 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. This proposed information collection was previously published

in the Federal Register on March 16, 2015, Volume 80, No.50, pages 13568-13569 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. The 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.

DIRECT COMMENTS TO OMB: 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, <u>OIRA\_submission@omb.eop.gov</u> or by fax to 202-395-6974, Attention: Desk Officer for NIH.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: contact Ms. Mikia Currie, Division of Grants Policy, 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: <a href="mailto:ProjectClearanceBranch@mail.nih.gov">ProjectClearanceBranch@mail.nih.gov</a>.

PROPOSED COLLECTION: Public Health Service (PHS) Post-award Reporting Requirements.

Revision, OMB 0925–0002, Expiration Date 8/31/2015. Form numbers: PHS 2590, PHS 416-7, PHS 2271, PHS 3734, PHS 6031-1, and HHS 568.

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 (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, 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. 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 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 531,802.

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	15	3,645		
RPPR	32,098	1	15	481,470		
Biosketch	2,544	1	2	5,088		
Data Tables	758	1	4	3,032		
PHS Inclusion Enrollment Report	2,544	1	1	2,544		
Trainee Diversity Report	480	1	15/60	120		
Publication Reporting	32,341	3	5/60	8,085		
PHS 3734	479	1	30/60	240		
Final Progress Report	11,125	1	1	11,125		
SBIR/STTR Phase II Final Progress Report	1,330	1	1	1,330		
Reporting Burden To	531,427					
RECORDKEEPING						
SBIR/STTR Life Cycle Certification	1,500	1	15/60	375		
Grand Total	531,802					

Dated: July 29, 2015.

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Deputy Director

National Institutes of Health

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