**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, 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.

**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.

**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:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia P. Currie, Project Clearance Branch, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 803-C, 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: projectclearancebranch@mail.nih.gov.

**SUPPLEMENTARY INFORMATION**: This proposed information collection was previously published in the Federal Register on April 12, 2019, Volume 84, No.71 pages 14958-14959 and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director, 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 3/31/2020, Office of the Director (OD), National Institutes of Health (NIH). This collection represents eliminating the Final Progress Report form as the form has been incorporated into the Final RPPR. Competing applications in the future may be updated to reflect related Human Fetal Tissue (HFT) information.

Need and Use of Information Collection: 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 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. 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.

*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 517,408.

**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 |

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|---|---|---|---|---|
| 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 374 | 479 | 1 | 30/60 | 240 |
| SBIR/STTR Phase II Final Progress Report | 1,330 | 1 | 1 | 1,330 |
| SBIR/STTR Life Cycle Certification | 1,500 | 1 | 15/60 | 375 |
| **Total** | | **218,983** | | **517,408** |

Dated: December 20, 2019.

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**Lawrence A. Tabak**,

*Principal Deputy Director,*

*National Institutes of Health.*

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