

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Mental Health; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, February 03, 2017, 10:00 a.m. to February 03, 2017, 03:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD, 20852 which was published in the **Federal Register** on January 18, 2017, 82 FR 5588.

This meeting notice is amended to change the meeting time to 10:30 a.m.–1:00 p.m. The meeting is closed to the public.

Dated: February 1, 2017.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2017-02429 Filed 2-6-17; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 02, 2017, 12:00 p.m. to March 02, 2017, 04:00 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, 7W538, Rockville, MD, 20850 which was published in the **Federal Register** on January 27, 2017, 82 FR 8620.

The meeting notice is amended to change the date of the meeting to March 8, 2017 from 12:00 p.m. to 4:00 p.m. The meeting is closed to the public.

Dated: February 1, 2017.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2017-02431 Filed 2-6-17; 8:45 am]

**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: 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 Email 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
<b>Reporting:</b>				
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
<b>Reporting Burden Total</b> .....				<b>499,033</b>
<b>Recordkeeping:</b>				
SBIR/STTR Life Cycle Certification .....	1,500	1	15/60	375
<b>Grand Total</b> .....				<b>519,408</b>

Dated: February 1, 2017.

**Lawrence A. Tabak,**  
Deputy Director, National Institutes of Health.  
[FR Doc. 2017-02471 Filed 2-6-17; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Mental Health; Amended Notice of Meeting**

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This meeting notice is amended to change the meeting time to 1:00 p.m.–5:00 p.m. The meeting is closed to the public.

Dated: February 1, 2017.

**Melanie J. Pantoja,**  
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-02430 Filed 2-6-17; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request PHS Applications and Pre-Award Reporting Requirements (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. This proposed information collection was previously published in the **Federal Register** on November 2, 2016, Volume 81, No. 212, pages 76368–76370 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