

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-16-121 Early-Stage Preclinical Validation of Therapeutic Leads for Diseases of Interest to the NIDDK (R01).

*Date:* November 17–18, 2016.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Antonello Pileggi, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, Bethesda, MD 20892-7892, (301) 402-6297, [pileggia@csr.nih.gov](mailto:pileggia@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-16-121 Early-Stage Preclinical Validation of Therapeutic Leads for Diseases of Interest to the NIDDK (R01).

*Date:* November 17, 2016.

*Time:* 11:30 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-1044, [chenhui@csr.nih.gov](mailto:chenhui@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Vascular and Hematology: Molecular and Cellular Hematology.

*Date:* November 30, 2016.

*Time:* 4:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Luis Espinoza, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301-435-0952, [espinozala@mail.nih.gov](mailto:espinozala@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Risk, Prevention and Health Behavior.

*Date:* December 1–2, 2016.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Claire E. Gutkin, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3106, MSC 7808, Bethesda, MD 20892, 301-594-3139, [gutkincl@csr.nih.gov](mailto:gutkincl@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Digestive Diseases.

*Date:* December 1–2, 2016.

*Time:* 8:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Jianxin Hu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2156, Bethesda, MD 20892, 301-827-4417, [jianxinh@csr.nih.gov](mailto:jianxinh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Kidney and Urology.

*Date:* December 1, 2016.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Aiping Zhao, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 2188, MSC 7818, Bethesda, MD 20892-7818, (301) 435-0682, [zhaoa2@csr.nih.gov](mailto:zhaoa2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; AREA: Immunology.

*Date:* December 1, 2016.

*Time:* 12:30 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review (CSR), National Institutes of Health (NIH), 6701 Rockledge Dr., Room 4203, Bethesda, MD 20817, (301) 435-3566, [alok.mulky@nih.gov](mailto:alok.mulky@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR16-027: Commercialization Readiness Pilot.

*Date:* December 2, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Washington Marriott at Metro Center, 775 12th Street NW., Washington, DC 20005.

*Contact Person:* Cristina Backman, Ph.D., Scientific Review Officer, ETTN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7846, Bethesda, MD 20892, [cbackman@mail.nih.gov](mailto:cbackman@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Mechanisms of Bacterial Virulence and Pathogenesis.

*Date:* December 2, 2016.

*Time:* 10:00 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301-435-1167, [pandyaga@mail.nih.gov](mailto:pandyaga@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 27, 2016.

**David Clary,**

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

[FR Doc. 2016-26451 Filed 11-1-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; 60-Day Comment Request; Public Health Service Applications and Pre-Award Reporting Requirements (Office of the Director)

**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 [trialsinfo@od.nih.gov](mailto:trialsinfo@od.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 to address 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) Applications and Pre-Award Reporting Requirements, Revision, OMB 0925-0001, Expiration Date 10/31/2018. Form numbers: PHS 398, PHS 416-1, PHS 416-5, and PHS 6031. This collection represents a consolidation of PHS applications and pre-award reporting requirements into a revised data collection under the PRA. This collection includes the proposed

use of a new PHS clinical trial application form.

*Need and Use of Information Collection:* This collection includes PHS applications and pre-award reporting requirements: PHS 398 (paper) Public Health Service Grant Application forms and instructions; PHS 398 (electronic) PHS Grant Application component forms and agency specific instructions used in combination with the SF424 (R&R); PHS Fellowship Supplemental Form and agency specific instructions used in combination with the SF424 (R&R) forms/instructions for Fellowships (electronic); PHS 416-1 Ruth L. Kirschstein National Research Service Award Individual Fellowship Application Instructions and Forms used only for a change of sponsoring institution application [paper]; Instructions for a Change of Sponsoring Institution for the National Research Service Award (NRSA) Fellowships (F30, F31, F32 and F33) and non-NRSA Fellowships; PHS 416-5 Ruth L. Kirschstein National Research Service Award Individual Fellowship Activation Notice; and PHS 6031 Payback Agreement. The PHS 398 (paper and electronic) are currently approved under 0925-0001. All forms expire 10/31/2018. Post-award reporting requirements are simultaneously consolidated under 0925-0002, and include the Research Performance Progress Report (RPPR). The PHS 398 and SF424 applications are used by applicants to request federal assistance funds for traditional investigator-initiated research projects and to request access to databases and other PHS resources. The PHS 416-1 is used only for a change of sponsoring institution application. PHS Fellowship Supplemental Form and agency specific instructions is used in combination with

the SF424 (R&R) forms/instructions for Fellowships and is used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The PHS 416-5 is used by individuals to indicate the start of their National Research Service Award (NRSA) awards. The PHS 6031 Payback Agreement is used by individuals at the time of activation to certify agreement to fulfill the payback provisions. 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 about proposed clinical trials in the PHS applications and pre-award reporting requirements will facilitate the NIH's oversight of clinical trials as well as assist in understanding where needs in the NIH research portfolio may exist. In addition, some of the data collected here will ultimately be accessible to investigators to pre-populate certain sections of forms when registering their trials with [ClinicalTrials.gov](http://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 850,756.

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
PHS 398—Paper .....	4,247	1	35	148,645
PHS 398/424—Electronic:				
PHS Assignment Request Form .....	37,120	1	30/60	18,560
PHS 398 Cover Page Supplement .....	74,239	1	1	74,239
PHS Inclusion Enrollment Report .....	54,838	1	1	54,838
PHS 398 Modular Budget .....	56,693	1	1	56,693
PHS 398 Training Budget .....	1,122	1	2	2,244
PHS 398 Training Subaward Budget Attachment(s) Form .....	561	1	90/60	842
PHS 398 Research Plan .....	70,866	1	3	212,598
PHS 398 Research Training Program Plan .....	1,122	1	3	3,366
Data Tables .....	1,515	1	4	6,060
PHS 398 Career Development Award Supplemental Form .....	2,251	1	3	6,753
PHS Clinical Trial Protocol Form .....	8,264	1	1	8,264
Biosketch (424 Electronic) .....	80,946	1	2	161,892
PHS Fellowship—Electronic:				
PHS Fellowship Supplemental Form (includes F reference letters) .....	6,707	1	12.5	83,838

## 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 Assignment Request Form .....	3,354	1	30/60	1,677
PHS Inclusion Enrollment Report .....	3,354	1	1	3,354
Biosketch (Fellowship) .....	6,707	1	2	13,414
416-1 .....	29	1	10	290
PHS 416-5 .....	6,707	1	5/60	559
PHS 6031 .....	6,217	1	5/60	518
VCOC Certification .....	6	1	5/60	1
SBIR/STTR Funding Agreement Certification .....	1,500	1	15/60	375
<b>Total Annual Burden Hours .....</b>		<b>420,101</b>		<b>850,756</b>

Dated: October 22, 2016.

**Lawrence A. Tabak,**

*Deputy Director, National Institutes of Health.*

[FR Doc. 2016-26448 Filed 11-1-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel.

*Date:* December 8, 2016.

*Time:* 9:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

*Contact Person:* Priscah Mujuru, DRPH, COHNS, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Suite 5B01, Bethesda, MD 20892-7510, 301-435-6908, [mujurup@mail.nih.gov](mailto:mujurup@mail.nih.gov). (Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research;

93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 27, 2016.

**Michelle Trout,**

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

[FR Doc. 2016-26386 Filed 11-1-16; 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, National Institutes of Health Electronic Application System for Certificates of Confidentiality

**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 August 18, 2016 (81 FR 55207-55208) 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](mailto: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: Dr. Ann Hardy, NIH Extramural Human Research Protections Officer and NIH Coordinator, Certificates of Confidentiality, 3701 Rockledge Dr. Rm. 3002, Bethesda, MD 20892, or call non-toll-free number (301) 435-2690 or Email your request, including your address to: [hardyan@od.nih.gov](mailto:hardyan@od.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Office of Extramural Research (OER), 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 of 1995, the NIH has submitted to the OMB a request for review and approval of the information collection listed below.

*Proposed Collection:* Certificate of Confidentiality Electronic Application System, 0925-0689, expiration date 01/31/2017, OER, NIH.

*Need and Use of Information Collection:* This application system provides one electronic form to be used by all research organizations that wish to request a Certificate of Confidentiality (CoC) from the NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the