

Time: 8:30 a.m. to 3:30 p.m.
Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton Washington DC Bethesda North, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301-435-1203, taupenol@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

Date: June 10–11, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW, Washington, DC 20036.

Contact Person: John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435-2398, pughjohn@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Gene and Drug Delivery Systems Study Section.

Date: June 12–13, 2019.

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

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Leslie S. Itsara, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, leslie.itsara@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: April 9, 2019.

Sylva L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-07341 Filed 4-11-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-1: NCI Clinical and Translational R21 and Omnibus R03.

Date: June 3, 2019.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Bethesda, MD 20892–9750, 240-276-5007, tandlea@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Moonshot: Inherited Cancer Syndromes.

Date: June 6, 2019.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W106, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Reed A. Graves, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Bethesda, MD 20892–9750, 240-276-6384, gravesr@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 8, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-07248 Filed 4-11-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; PHS Applications and Pre-Award Reporting Requirements (OD)

AGENCY: National Institutes of Health, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for 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, Chief, Project Clearance Branch (PCB), Office of Policy for Extramural Research Administration (OPERA), 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 ProjectClearanceBranch@mail.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 on 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 3/31/2020, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Starting in January 2020, NIH will require applicants and recipients to address Human Fetal Tissue requirements within the SF–424 R&R and the Research Performance Progress Report (RPPR) due to Congressional ((Sections 498A and 498B of the PHS Act (42 U.S.C. 289g–1 and 289g–2)) and Department of Health and Human Services (45 CFR 46.204 and 46.206) mandates regarding human fetal tissue research. Applicants and recipients will be required to comply with Federal and state laws concerning the acquisition of human fetal tissue (including cell lines) as well as include a concise description of the proposed characteristics of the human fetal cells/ tissue outlining the procurement budget details, and how the applicants/ recipients will document the processes for how they will use the human fetal tissues and cells. Additionally, this revision will clarify information regarding an institutional commitment to ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices. This collection also continues to include 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 (NRSA) Individual Fellowship Application Instructions and Forms used only for a change of sponsoring institution application [paper]; Instructions for a Change of Sponsoring Institution for 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 3/31/2020. 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 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 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 will facilitate NIH's development of data systems to facilitate oversight of clinical trials as well as understand where gaps in the 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*.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,150,389.

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 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 | 10 | 708,660 |
| PHS 398 Research Training Program Plan | 1,122 | 1 | 10 | 11,220 |
| Data Tables | 1,515 | 1 | 4 | 6,060 |
| PHS 398 Career Development Award Supplemental Form | 2,251 | 1 | 10 | 22,510 |
| PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment report) | 54,838 | 1 | 14 | 767,732 |
| 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 |
| PHS Assignment Request Form | 3,354 | 1 | 30/60 | 1,677 |
| PHS Human Subjects and Clinical Trial Information (includes inclusion enrollment report) | 5,030 | 1 | 14 | 70,420 |
| 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 |

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 |
|---|-----------------------|------------------------------------|--|---------------------------|
| VCOC Certification | 6 | 1 | 5/60 | 1 |
| SBIR/STTR Funding Agreement Certification | 1,500 | 1 | 15/60 | 375 |
| Total Annual Burden Hours | 421,777 | 421,777 | | 2,150,389 |

Dated: April 5, 2019.
Lawrence A. Tabak,
Deputy Director, National Institutes of Health.
 [FR Doc. 2019-07324 Filed 4-11-19; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Post-Award Reporting Requirements Including Research Performance Progress Report Collection (OD)

AGENCY: National Institutes of Health, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for 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 ProjectClearanceBranch@mail.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 on 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) Post-award Reporting Requirements Revision, OMB 0925-0002, Expiration Date 3/31/2020, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Starting in January 2020, NIH will require applicants and recipients to address Human Fetal Tissue requirements within the SF-424 R&R and the Research Performance Progress Report (RPPR) due to Congressional ((Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2)) and Department of Health and Human Services (45 CFR 46.204 and 46.206) mandates regarding human fetal tissue research. Applicants and recipients will be required to comply with Federal and state laws concerning the acquisition of human fetal tissue (including cell lines) as well as include a concise description of the proposed characteristics of the human fetal cells/tissue outlining the procurement budget details, and how the applicants/recipients will document the processes for how they will use the human fetal tissues and cells. Additionally, this revision will clarify information regarding an institutional commitment to ensuring that proper policies, procedures, and oversight are in place to

prevent discriminatory harassment and other discriminatory practices. 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 National Research Service Award (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