DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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/or contract proposals 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 Initial Review Group; Reproduction, Andrology, and Gynecology Subcommittee.

Date: June 18, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NICHD Offices, 6710B Rockledge Drive, Room 2125B, Bethesda, MD 20892 (Video-Assisted Meeting).

Contact Person: Derek J. McLean, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2125B, Bethesda, MD 20892–7002, (301) 443–5082, *derek.mclean@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Pediatrics Subcommittee.

Date: June 24, 2021.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NICHD Offices, 6710B Rockledge Drive, Room 2125C, Bethesda, MD 20892 (Video-Assisted Meeting).

Contact Person: Joanna Kubler-Kielb, Ph.D., Scientific Review Officer, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm 2125C, Bethesda, MD 20817, 301–435–6916, *kielbj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: April 7, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07435 Filed 4–9–21; 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, 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 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 clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Function, Integration, and Rehabilitation Sciences Subcommittee.

Date: June 25, 2021.

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

Agenda: To review and evaluate grant applications.

Place: NICHD/NIH, 6710B Rockledge Drive, Bethesda, MD 20892 (Video-Assisted Meeting).

Contact Person: Helen Huang, Ph.D., Scientific Review Officer, Eunice Kennedy Shriver, National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2137D, Bethesda, MD 20892, 301–435–8207, *helen.huang@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: April 6, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07378 Filed 4–9–21; 8:45 am]

BILLING CODE 4140–01–P

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 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of propose 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) Applications and Pre-Award Reporting Requirements, Revision, OMB 0925–0001, Expiration Date 2/28/2023, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: This collection is being revised to omit the Inclusion Enrollment Report form, which is being converted to a Common form to include the Department of Defense (DoD). The Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants. Starting in January 2022, NIH will require will applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number. Also, the application forms will be updated to align with the *Grants.gov* updated Country and State lists. NIH also anticipates adding an optional field to the end of our forms and applications to get a more accurate assessment of the time it takes our applicants to complete the various forms and applications. This collection also continues to 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 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 2/28/2023. 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 2,090,521.

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	54,838	1	13	712,894
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	5,030	1	13	65,390
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
Total Annual Burden Hours		421,777		2,090,521

Dated: April 4, 2021.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2021–07396 Filed 4–9–21; 8:45 am]

BILLING CODE 4140–01–P

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 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of propose 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 Including Research Performance Progress Report (RPPR) Collection, Revision, OMB 0925–0002, Expiration Date 2/28/2023, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: This collection is being revised because starting in January 2022, NIH will require will applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number. Also, the application forms will be updated to align with the *Grants.gov* updated Country and State lists. NIH also anticipates adding an optional field to the end of our forms and applications to get a more accurate assessment of the time it takes our applicants to complete the various forms and applications. 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 is 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 535,579.

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