

§ 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 19, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21836 Filed 9–23–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Building Interdisciplinary Research Careers in Women’s Health (BIRCWH)

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) is an institutional mentored career-development program designed to connect junior faculty, known as BIRCWH Scholars, to senior faculty mentors with shared interest in women’s health and sex differences research. The BIRCWH Annual Meeting is a gathering of senior and junior faculty that provides an opportunity to network and share scientific advances.

**DATES:** The meeting will be held on October 1, 2024, from 8 a.m. to 5 p.m. EDT.

**ADDRESSES:** The meeting will be in person; registration is at <https://www.eventbrite.com/e/2024-bircwh-annual-meeting-tickets-893884130497>. The meeting is viewable at <https://videocast.nih.gov/watch=55110>.

**FOR FURTHER INFORMATION CONTACT:** For information concerning this meeting, visit <https://orwh.od.nih.gov/about/newsroom/events/2024-building-interdisciplinary-research-careers-in-womens-health-bircwh-annual-meeting>, or contact Dr. Marquitta White, Senior Research Program Officer, Careers

Section, in the Office of Research on Women’s Health (ORWH), 6707 Democracy Boulevard, Suite 400, Bethesda, MD 20817, telephone: 301–402–1770; email: [marquitta.white@nih.gov](mailto:marquitta.white@nih.gov).

**SUPPLEMENTARY INFORMATION:** This notice is in accordance with 42 U.S.C. 287d of the Public Health Service Act, as amended. Created by the ORWH in partnership with NIH Institutes, Centers, and Offices.

This year, the BIRCWH abstracts have been grouped into nine categories with the following number of abstracts, from highest to lowest: Public Health (12), Reproductive Health (10), Sex and Gender Differences (9), Health Disparities (9), Cancer (9), Neuroscience (8), Clinical Research (7), Basic Research (6), and Bioengineering/Bioinformatics (3). The number and quality of abstracts centered on Public Health and Basic Research has increased this year, indicating a growing focus on women’s health and the influence of biological sex on health and disease in these important areas. Specifically, several abstracts in these categories focus on maternal morbidity, perinatal health, and how biological sex and gender transition impact health and disease. The meeting will include the 2024 Ruth L. Kirschstein Memorial Lecture by Abbey B. Berenson M.D., MMS, Ph.D., and the 2024 Legacy of Leadership Lecture by Nina F. Schor, M.D., Ph.D.

Individuals interested in in-person attendance can register online at <https://www.eventbrite.com/e/2024-bircwh-annual-meeting-tickets-893884130497>.

More information about the speakers and agenda can be found at <https://orwh.od.nih.gov/about/newsroom/events/2024-building-interdisciplinary-research-careers-in-womens-health-bircwh-annual-meeting>.

This event is free.

Dated: September 16, 2024.

**Lawrence A. Tabak,**

*Principal Deputy Director, National Institutes of Health.*

[FR Doc. 2024–21717 Filed 9–23–24; 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; Public Health Service (PHS) 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, 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.

**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 recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**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](mailto:ProjectClearanceBranch@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the **Federal Register** on May 22, 2024, pages 45001–45003 (89 FR 45001) 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.

The Office of the Director (OD), Office of Extramural Research (OER), 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 Office of Management and Budget (OMB) control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, NIH has submitted to OMB a request for review and approval of the information collection listed below.

*Proposed Collection Title:* Public Health Service (PHS) Applications and

Pre-Award Reporting Requirements, Revision, OMB 0925–0001, Expiration Date 01/31/2026, Office of the Director (OD), National Institutes of Health (NIH).

**Need and Use of Information Collection:** Effective for due dates on or after January 25, 2025, NIH will be implementing several trans-NIH initiatives to simplify the grants process for applicants and recipients as well as for peer review. NIH will be updating fellowship applications to improve fellowship peer review to facilitate the mission of these programs to identify the most promising candidates and individualized training opportunities that will assist them along their paths to support the advancement of the biomedical research enterprise. NIH will be reducing the number of required attachments and updating instructions for the PHS Fellowship Supplemental Form to align with the revised scored review criteria. NIH will also be updating institutional training grant applications, including adding a new attachment field to the PHS 398 Research Training Program Plan form for the transparent collection of the Recruitment Plan to Enhance Diversity while also providing additional space for applicants within the Program Plan page limit where this information was previously collected. The Training Data Tables will also be updated to reduce burden and promote consistent information collection, including limiting the scope of information collection to data only relevant to the training stage(s) of the proposed program in table 1 and removing instructions in table 8 that are reported within the Research Performance Progress Report (RPPR). Effective for

due dates on or after May 25, 2025, NIH will be adopting the Common Forms for Biographical Sketch and Current and Pending (Other) Support as part of the directive from Guidance for Implementing National Security Presidential Memorandum (NSPM)-33. The Common Forms are part of a separate OMB collection, currently approved under 3145–0279. As such, elements that will be collected within the Common Forms will be removed from NIH’s current NIH Biosketch and Other Support formats. NIH will continue to collect additional information not captured on the Common Forms to adhere to the agency’s implementation of the NIH Peer Review Regulations at 42 CFR part 52 as part of the NIH Biosketch form, which will be renamed the NIH Biographical Sketch Supplement to reflect the supplemental information requested. The application and progress report forms and associated instructions will be updated to align with these new requirements. 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 Research & Related (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 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 01/31/2026. Post-award reporting requirements are simultaneously consolidated under 0925–0002 and include the 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,175,670.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
PHS 398—Paper .....	Grant Applicant .....	4,247	1	35	148,645
<b>PHS 398/424—Electronic</b>					
PHS Assignment Request Form .....	Grant Applicant .....	37,120	1	30/60	18,560
PHS 398 Cover Page Supplement .....	Grant Applicant .....	74,239	1	1	74,239
PHS 398 Modular Budget .....	Grant Applicant .....	56,693	1	1	56,693
PHS 398 Training Budget .....	Grant Applicant .....	1,122	1	2	2,244
PHS 398 Training Subaward Budget Attachment(s) Form.	Grant Applicant .....	561	1	90/60	842
PHS 398 Research Plan .....	Grant Applicant .....	70,866	1	10	708,660
PHS 398 Research Training Program Plan .....	Grant Applicant .....	1,122	1	10	11,220
Data Tables .....	Grant Applicant .....	1,515	1	4	6,060
PHS 398 Career Development Award Supplemental Form.	Grant Applicant .....	2,251	1	10	22,510
PHS Human Subjects and Clinical Trial Information.	Grant Applicant .....	54,838	1	13	712,894
Biosketch (424 Electronic) .....	Grant Applicant .....	80,946	1	2	161,892

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Data Management and Sharing Plan .....	Grant Applicant .....	73,117	1	2	146,234
VCOC Certification .....	Grant Applicant .....	6	1	5/60	1
SBIR/STTR Funding Agreement Certification .....	Grant Applicant .....	1,500	1	15/60	375
<b>PHS Fellowship—Electronic</b>					
PHS Fellowship Supplemental Form (includes F reference letters).	Fellowship Grant Applicant.	6,707	1	13	87,191
Biosketch (Fellowship) .....	Fellowship Grant Applicant.	6,707	1	2	13,414
416-1 .....	Fellowship Grant Applicant.	29	1	10	290
PHS 416-5 .....	Fellowship Grant Applicant.	6,707	1	5/60	559
PHS 6031 .....	Fellowship Grant Applicant.	6,217	1	5/60	518
<b>NIH Other Transaction</b>					
NIH Other Transaction Application Form .....	Other Transaction Applicant.	239	1	11	2,629
<b>Total</b> .....	.....	<b>486,749</b>	<b>486,749</b>	.....	<b>2,175,670</b>

Dated: September 16, 2024.

**Lawrence A. Tabak,**  
Principal Deputy Director, National Institutes of Health.  
[FR Doc. 2024-21801 Filed 9-23-24; 8:45 am]  
BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting**

Pursuant to section 1009 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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Cystic Fibrosis Research and Translation Centers.

*Date:* October 31–November 1, 2024.  
*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.  
*Place:* National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).  
*Contact Person:* Ryan G. Morris, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, 6707 Democracy Boulevard, Rm 7015, Bethesda, MD 20892-2542, 301-594-4721, [ryan.morris@nih.gov](mailto:ryan.morris@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: September 18, 2024.  
**Miguelina Perez,**  
Program Analyst, Office of Federal Advisory Committee Policy.  
[FR Doc. 2024-21739 Filed 9-23-24; 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 (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, 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.

**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 recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**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](mailto:ProjectClearanceBranch@mail.nih.gov). Formal requests for additional plans and