

Bank (NPDB) self-query results. The supplemental fee will increase from \$3.00 to \$13.00 per mailed paper copy as these copies will be provided using U.S. Postal Service certified mail. The user fees for one-time query, continuous, and digitally certified self-query results will remain unchanged.

DATES: The fee increase for mailed paper self-query results will be effective October 1, 2024.

FOR FURTHER INFORMATION CONTACT: David Loewenstein, Director, Division of Practitioner Data Bank, Bureau of Health Workforce, HRSA, (301) 443-2300, NPDBPolicy@hrsa.gov.

SUPPLEMENTARY INFORMATION: The current fee structure (\$2.50/continuous query enrollment, \$2.50/one-time query, and \$3.00/self-query and an additional \$3.00/requested mailed paper copy) was announced in the **Federal Register** on July 21, 2021, (86 FR 38491) and became effective on October 1, 2021. One-time queries, continuous query enrollments, and self-queries are submitted and query responses are received through the NPDB's secure website. Fees are paid via electronic funds transfer, debit card, or credit card.

The user fees for one-time query, continuous, and digitally certified self-query results will remain unchanged. Upon requesting a self-query, practitioners receive a digitally certified response which they can save and provide to requesting entities electronically. Digitally certified self-queries are delivered in an unalterable PDF within minutes of the request being placed. Practitioners can save their certified response file digitally and provide it to requesting entities directly. The security of a digitally certified response provides assurance that the response is exactly as it was issued by the NPDB. However, if needed, practitioners may also request a mailed paper copy of their self-query results. To protect sensitive information in self-query responses, the mailed results will now be delivered through U.S. Postal Service certified mail with receipt confirmation. Since the NPDB is required to cover all its costs with user fees, increased fee for mailed paper self-query results will offset the certified mail expense.

HRSA operational standards require review of NPDB user fees at least every 2 years. The biennial review of NPDB user fees offers HRSA the opportunity to evaluate its reserves as well as revenue relative to costs. Further, the review provides essential information on whether the fee rates and authorized activities are aligned with actual program costs and activities, and can

help promote greater understanding of the fee by NPDB users.

The NPDB is authorized by the Health Care Quality Improvement Act of 1986 (the Act), Title IV of Public Law 99-660, as amended (42 U.S.C. 11101 *et seq.*). Further, two additional statutes expanded the scope of the NPDB—Section 1921 of the Social Security Act, as amended (42 U.S.C. 1396r-2) and Section 1128E of the Social Security Act, as amended (42 U.S.C. 1320a-7e). Information collected under the Section 1128E authority was consolidated within the NPDB pursuant to Section 6403 of the Affordable Care Act, Public Law 111-148; this consolidation became effective on May 6, 2013. 42 U.S.C. 11137(b)(4), 42 U.S.C. 1396r-2(e), and 42 U.S.C. 1320a-7e(d) authorize the establishment of fees for the costs of processing requests for disclosure of such information. Final regulations at 45 CFR part 60 set forth the criteria and procedures for information to be reported to and disclosed by the NPDB. In determining any changes in the amount of user fees, the Department uses the criteria set forth in section 60.19(b) of the regulations. Section 60.19(b) states:

“The amount of each fee will be determined based on the following criteria:

- (1) Direct and indirect personnel costs, including salaries and fringe benefits such as medical insurance and retirement,
- (2) Physical overhead, consulting, and other indirect costs (including materials and supplies, utilities, insurance, travel, and rent and depreciation on land, buildings, and equipment),
- (3) Agency management and supervisory costs,
- (4) Costs of enforcement, research, and establishment of regulations and guidance,
- (5) Use of electronic data processing equipment to collect and maintain information—the actual cost of the service, including computer search time, runs and printouts, and
- (6) Any other direct or indirect costs related to the provision of services.”

The Department will continue to review the user fees periodically as required by Office of Management and Budget Circular Number A-25 and will revise fees as necessary. Any future changes in user fees and their effective dates will be announced in the **Federal Register**.

Carole Johnson,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0260]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 18, 2024.

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. 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: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 264-0041, or PRA@HHS.GOV. When submitting comments or requesting information, please include the document identifier 0990-0260-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation.

Type of Collection: Extension of a currently approved collection.

OMB No.: 0990-0260.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed

Consent/Consent Documentation, OMB No. 0990-0260.

Information reported to the Federal departments and agencies under the Common Rule with respect to a satisfactory assurance is used to ensure that an institution engaged in non-exempt research involving human subjects conducted or supported by a Common Rule department or agency has

(1) established adequate administrative policies and procedures for protecting the rights and welfare of human subjects in research, and (2) accepts that responsibility. Other reporting requirements are used to: assess whether the institution is following the established procedures; ensure that Federal funds are not expended for unapproved human subjects research;

and, determine if the approved status of an awarded grant, contract, or cooperative agreement should be reviewed, with the ultimate goal of maintaining or increasing human subject protections.

Likely Respondents: Institutions and institutional review boards.

Annualized Burden Hour Tables

TABLE 1—ESTIMATED ANNUAL IRB RECORDKEEPING BURDEN

Common rule provision	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
.115 [Pre-2018 and 2018 Requirement]—Preparation and documentation of IRB activities	6,000	16	96,000	12	1,152,000
Total	96,000	1,152,000

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
.109(d) [Pre-2018 and 2018 Requirements]—Written notification of IRB approval or disapproval of research	6,000	25	150,000	0.5	75,000
.116(a) and (b) (Pre-2018 Requirements)/.116 (b), (c) and (d) [2018 Requirements]—Elements of informed consent and broad consent	6,000	25	150,000	0.5	75,000
.116(h)—[2018 Requirements]—Posting clinical trial consent form	425	5	2,125	0.5	1,063
.117(a) [Pre-2018 and 2018 Requirements]—Documentation of informed consent	6,000	20	120,000	0.5	60,000
.117(c)(2) [Pre-2018 and 2018 Requirements]—Written statement about the research when informed consent documentation is waived	6,000	5	30,000	.5	15,000
Total	452,125	226,063

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024-18447 Filed 8-16-24; 8:45 am]

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Dated: August 13, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

Name of Committee: Advisory Committee on Research on Women’s Health.

Date: October 8, 2024.

Time: 9:00 a.m. to 4:30 p.m.

Agenda: ORWH Director’s Report, Presentation from NIBIB and SEED Office Directors, Panel discussion on technology, engineering and, innovation in women’s health, presentation from the U.S. National Science Foundation’s Directorate for Engineering Director, presentations of concepts for Advisory Committee clearance including Funding Opportunities to Support Research on Chronic Female-Specific and Gynecologic Conditions and Careers of Women.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Contact Person: Vivian Ota Wang, Ph.D., FACMG, CGC, Deputy Director, Office on Research for Women’s Health, Division of Program Coordination, Planning and

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Library of Medicine Board of Scientific Counselors, November 7, 2024, 11:00 a.m. to 2:30 p.m., which was published in the **Federal Register** on July 15, 2024, 89 FR 135, Page Number 57422.

This notice is being amended to announce that the meeting date will be changed from November 7, 2024, to November 6, 2024. The meeting will be virtual.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee on Research on Women’s Health.

The meeting will be open to the public as a virtual meeting. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact