

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.

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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