

methods including email and FDA’s eSubmitter program (<https://www.fda.gov/industry/fda-esubmitter>).

FDA issued part 810 to implement the provisions of section 518 of the FD&C Act. The information collected under the mandatory recall authority

provisions is used by FDA to implement mandatory recalls.

*Description of Respondents:* Respondents for this collection of information are firms, including medical device manufacturers, importers, distributors, and retailers, that have been issued a cease

distribution and notification order or mandatory recall order in accordance with the provisions under part 810, during the timeframe(s) specified in the order.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Collection activity—21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of information to FDA about device distribution and remedial actions to be taken, as specified in the order—810.10(d) .....	2	1	2	8	16
Submission of a written request for regulatory hearing—810.11(a) .....	1	1	1	8	8
Submission of a written request to FDA asking that the order be modified or vacated—810.12(a–b) .....	1	1	1	8	8
Submission of a strategy for compliance with cease distribution and notification or mandatory recall order—810.14 .....	2	1	2	16	32
Submission of periodic status reports to FDA to enable the agency to assess progress in compliance with the order—810.16(a–b) .....	2	12	24	40	960
Submission of a written request to FDA to certify compliance with and terminate the order—810.17(a) .....	2	1	2	8	16
<b>Total Hours</b> .....					<b>1,040</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Collection activity—21 CFR section	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Documentation of communications to appropriate person(s)—810.15(b) .....	2	1	2	8	16

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Collection activity—21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Communications to appropriate person(s) concerning a cease distribution and notification or mandatory recall order—810.15(a)–(c) .....	2	1	2	12	24
Follow up communications to appropriate person(s) who fail to respond to the initial communication—810.15(d) .....	2	1	2	4	8
Notifications provided by recipients of communications to appropriate consignees—810.15(e) .....	10	1	10	1	10
<b>Total</b> .....					<b>42</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden per response, burden per recordkeeping, and burden per disclosure estimates are based on FDA’s recent experience with voluntary recalls under 21 CFR part 7. Based on an analysis of cease distribution and notification and mandatory recall order activity over the last 3 years, FDA expects no more than two of such actions per year as a conservative estimate.

Based on a review of the information collection since our last request for

OMB approval, we have made no adjustments to our burden estimate.

Dated: May 31, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–12346 Filed 6–4–24; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS–0990–new]

**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 July 5, 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](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:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 264–0041, or [PRA@HHS.GOV](mailto:PRA@HHS.GOV). When submitting comments or requesting information, please include the document identifier 0990–New–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:* OASH Performance Project Report for Grants and Cooperative Agreements.

*Type of Collection:* New.

OMB No. 0990–NEW—Office of the Assistant Secretary for Health

*Abstract:* The Office of the Assistant Secretary for Health (OASH) is seeking OMB approval on a new information collection, the OASH Periodic Performance Project Report for Grants and Cooperative Agreements (hereafter the OASH PPR). The purpose of this data collection is to gather quantitative and qualitative information common to the assessment of recipient performance on individual grants and cooperative agreements (collectively, grants) managed in OASH. OASH will collect common data elements measuring the performance of each recipient against the approved grant project plan,

including progress toward goals and outcomes as required by 45 CFR 75.342(b)(2).

OASH oversees a broad range of grant programs within the Office of the Secretary (OS), Department of Health and Human Services (HHS). The current active OASH programs with discretionary grants (with assistance listing number) include: Public Awareness Campaigns on Embryo Adoption (93.007); Research on Research Integrity (93.085); Advancing System Improvements for Key Issues in Women’s Health (93.088); Community Programs to Improve Minority Health Grant Programs (93.137); Family Planning Services (93.217); Family Planning Personnel Training (93.260); Teenage Pregnancy Prevention Program (93.297); Public Health Service Evaluation Funds (93.343); Research, Monitoring and Outcomes Definitions for Vaccine Safety (93.344); Minority HIV/AIDS Fund (93.899); Family Planning Service Delivery Improvement Research Grants (93.974); and National Health Promotion (93.990). OASH grants span a wide range of project types, including service, demonstration project, evaluation, research, training, and conference projects. Within each program, the awards are subdivided into cohorts aligned with the notices of funding opportunity under which OASH competed the awards. Currently, there are 47 cohorts of active awards across OASH. In any given year, OASH programs collectively monitor 450–550 active awards with another 200–300 inactive awards awaiting final reports as a prerequisite to closing the grant.

The collection is needed to enhance project performance information and simplify reporting under 45 CFR 75.301. Each recipient currently must submit a quarterly Federal Financial Report (FFR or SF–425)(45 CFR 75.341) and a periodic Performance Progress Report (PPR) for each grant (45 CFR 75.342(b)(2)). PPR reporting periods in OASH are scheduled quarterly, semi-annually, or annually, depending on the need determined by the program office using a narrative format that can vary by cohort. The PPR schedule is specifically aligned with the quarterly FFRs whenever possible to create a complete snapshot of the project’s progress at the end of the reporting period.

The common elements identified in the new collection for OASH programs

will standardize the collection of the required information (45 CFR 75.342(b)(2)) including: (1) a comparison of the actual accomplishments to the objectives of the award for the period; (2) the reasons why established goals were not met; and (3) pertinent information, analysis and explanation of cost overruns or high unit costs. The common elements include reporting on publications, including data sets and other work products, to facilitate implementation of OSTP Memorandum Ensuring Free, Immediate, and Equitable Access Federally Funded Research (August 25, 2022). The new information collection will limit the content of the report to those activities taking place during the reporting period (*i.e.*, quarterly, semiannually, or annually). The information collection is structured to facilitate program review across reporting periods. This will allow OASH to identify and improve program outcomes, share lessons learned, and spread the adoption of promising practices among its grant recipients and other HHS awarding agencies.

The content of the new collection is structured for web-based data collection under 7 headings: Report Header; Project Progress; Significant Project Accomplishments; Broader Program Impacts; Products and Dissemination; Collaboration and Partnering Activities; and Project Evaluation Activities. Information will be prepopulated based on the login credentials for the user submitting the report and the specific grant being reported. Not all grants will have reportable activities under all headings (*e.g.*, not all grants have an evaluation component embedded in the project). However, most OASH grants will have reportable information under most headings. Program offices with additional reporting programmatic information collections will eventually transition collection of any overlapping data elements to this OASH PPR. During the transition, OASH will not require grant recipients to provide the same information twice.

*Likely Respondents:* Members and staff from academia, community organizations, local/State/Federal government, private sector, and tribal government and services organizations including those who serve American Indian and Alaska Native and/or racial and ethnic minorities.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
OASH grant recipients .....	800	3	1	2,400
Total .....	800	3	1	2,400

**Sherrette A. Funn,**  
*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*  
 [FR Doc. 2024-12273 Filed 6-4-24; 8:45 am]  
**BILLING CODE 4150-34-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 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 the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Oncology 2—Translational Clinical Integrated Review Group; Cancer Prevention Study Section.

*Date:* June 27–28, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Byung Min Chung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-4056, [justin.chung@nih.gov](mailto:justin.chung@nih.gov).

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.

*Date:* June 27–28, 2024.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Zarana Patel, Ph.D., MPH Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-9295, [zarana.patel@nih.gov](mailto:zarana.patel@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR-24-045 and PAR-24-046: Tackling Acquisition of Language in Kids (TALK) applications.

*Date:* June 27, 2024.

*Time:* 9:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Rochelle Francine Hentges, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000C, Bethesda, MD 20892, (301) 402-8720, [hentgesrf@mail.nih.gov](mailto:hentgesrf@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Neuroimaging Technologies.

*Date:* June 27–28, 2024.

*Time:* 9:30 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Raj K. Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, MSC 7804, Bethesda, MD 20892, (301) 435-1047, [kkrishna@csr.nih.gov](mailto:kkrishna@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Genes, Genomes and Genetics.

*Date:* June 27–28, 2024.

*Time:* 10:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Linda Wagner Jurata, Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-8032 [linda.jurata@nih.gov](mailto:linda.jurata@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: The Cellular and Molecular Biology of Complex Brain Disorders.

*Date:* June 27–28, 2024.

*Time:* 10:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Adem Can, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850 Bethesda, MD 20892, (301) 435-1042, [cana2@csr.nih.gov](mailto:cana2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Epidemiology and Population Sciences.

*Date:* June 27–28, 2024.

*Time:* 10:00 a.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (In Person and Virtual Meeting).

*Contact Person:* Rebecca I. Tinker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 435-0637, [tinkerri@csr.nih.gov](mailto:tinkerri@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Cerebrovascular Disorders, Epilepsy and Neural Injury.

*Date:* June 27, 2024.

*Time:* 10:00 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Paula Elyse Schauwecker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5201 Bethesda, MD 20892, 301-760-8207, [schauweckerpe@csr.nih.gov](mailto:schauweckerpe@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Cellular Immunology, Transplantation and Viremia.

*Date:* June 27, 2024.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Philip Owens, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr. Bethesda, MD 20892, (301) 594-7394, [owensp2@csr.nih.gov](mailto:owensp2@csr.nih.gov).

*Name of Committee:* Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

*Date:* June 27–28, 2024.

*Time:* 12:30 p.m. to 8:30 p.m.