Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312, pertaining to the submission of investigational new drug applications, and submission of supporting nonclinical, preclinical and clinical data, including a pediatric clinical development plan, have been approved under OMB control number 0910–0014. The collections of information for FDA approval to market new drugs in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information for FDA licensure of biological products in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 58 pertaining to good laboratory practice have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18407 Filed 9–22–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Behavioral Health Integration Evidence Based Telehealth Network Program Integration Telehealth Evidence Collection Tool, OMB No. 0906–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 24, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Behavioral Health Integration Evidence Based Telehealth Network Program Integration Telehealth Evidence Collection Tool, OMB No. 0906–xxxx—New.

Abstract: This clearance request is for OMB approval of a new information collection, the Behavioral Health Integration Evidence Based Telehealth Network Program (BHI EB–TNP) Integration Telehealth Evidence Collection Tool. Under the BHI EB–TNP, HRSA administers grants in accordance with section 330I(d)(1) of the Public Health Service Act (42 U.S.C. 254c–14(d)(1)). The purpose of the BHI EP–TNP program is to integrate behavioral health services into primary care settings using telehealth technology through telehealth networks and evaluate the effectiveness of such integration. This program supports evidence-based projects that utilize telehealth technologies through telehealth networks in rural and underserved areas to: (1) improve access to integrated behavioral health services in primary care settings, and (2) expand and improve the quality of health information available to health care providers by evaluating the effectiveness of integrating telebehavioral health services into primary care settings and establishing an evidence-based model that can assist health care providers.

HRSA collaborated with grantees in the development of a set of outcome measures to evaluate the effectiveness of grantees' telebehavioral services and monitor grantees' progress/effectiveness by analyzing performance reporting data. The measures address behavioral health and substance use disorder priorities and will help to assess the effectiveness of evidence-based practices with the use of telehealth for patients, providers, and payers. The data collection instrument will include 27 total data elements addressing patient encounter information.

Need and Proposed Use of the Information: HRSA developed the BHI EB–TNP instrument with the program's four goals in mind:

(1) Improving access to the behavioral health services needed,

(2) Reducing rural and underserved population practitioner isolation,

(3) Improving health system productivity and efficiency, and

(4) Improving patient outcomes.

HRSA worked with program grantees to develop outcome measures to evaluate and monitor the progress of the grantees in each of these categories, with specific indicators to be reported annually through a performance monitoring data collection platform/website. Measures capture awardee-level and aggregate data that illustrate the impact and scope of program funding along with assessing these efforts. The measures are intended to inform HRSA's progress toward meeting program goals, specifically improving access to telebehavioral health services that support primary care providers.

Likely Respondents: BHI EB–TNP grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
BHI EB–TNP Outcome Measurement Report	27	1	27	69	1,863
Total	27		27		1,863

HRSA specifically requests comments on: (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–18397 Filed 9–22–25; 8:45 am]

BILLING CODE 4165–15–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: Center for Scientific Review Special Emphasis Panel; RFA Panel: Small Grant Program for NHLBI K Award Recipients (R03).

Date: November 14, 2025.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Dmitri V Gnatenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *gnatenkod2@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Services and Systems.

Date: November 14, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Shareen Iqbal, MPH, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 496–6937, *shareen.iqbal@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in basic neurovascular biology, neurodegeneration, and neurological disorders.

Date: November 14, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Gagan Deep Bajaj, Ph.D., Scientific Review Officer, National Institute on Drug Abuse, NIH, Scientific Review Branch, 11601 Landsdown Street, 3WF Room 09A01, Bethesda, MD 20892, (301) 402–6965, *gagan.bajaj@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–AI–24–080 Broad Spectrum Products Against Multiple Neurotoxin Botulinum Serotypes (R61/R33 Clinical Trial Not Allowed).

Date: November 14, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Soheyla Saadi, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20892, (240) 669–5178, *saadisoh@niaid.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

Date: November 18–19, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Yuanyi Feng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594–1180, *fengy7@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biobehavioral Processes.

Date: November 18–19, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jeanne M McCaffery, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3854, *jeanne.mccaffery@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Health Services and Systems: Career Development Award Grant Review.

Date: November 18–19, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Claudio Dario Ortiz, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (240) 869–9245, *claudio.ortiz@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special: Clinical studies and Coordinating Centers.

Date: November 18, 2025.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Nawazish Ali Naqvi, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–