

information in 21 CFR 312.23 regarding investigational new drug applications, including clinical trial design and study protocols, have been approved under OMB control number 0910-0014. The collections of information in 21 CFR parts 50 and 56 regarding institutional review boards and the protection of human subjects have been approved under OMB control number 0910-0130. The collections of information in 21 CFR part 11 regarding electronic records and signatures have been approved under OMB control number 0910-0303. The collections of information described in FDA's guidance entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products" (<https://www.fda.gov/media/109951/download>) have been approved under OMB control number 0910-0429.

### III. Additional Information

Section 3002 of Title III, Subtitle A, of the 21st Century Cures Act (Pub. L. 114-255) directs FDA to develop patient-focused drug development guidance to address a number of areas, including under section 3002(c)(2):

Methodological approaches that may be used to develop and identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease.

In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and

other public stakeholders, as part of negotiations with regulated industry. Section I.J.1 of the commitment letter "Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making" (<https://www.fda.gov/media/99140/download>) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision-making.

### IV. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-20153 Filed 11-17-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Notice of Supplemental Funding; Rural Residency Planning and Development Technical Assistance

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

**ACTION:** Notice of supplemental funding.

**SUMMARY:** HRSA provided supplemental funds to the Rural Residency Planning and Development (RRPD-TA) recipient under HRSA-25-008 to provide additional technical assistance on rural residency program development and support the improvement of health care in rural areas.

#### FOR FURTHER INFORMATION CONTACT:

Jason Steele, RRPD Program Coordinator, Federal Office of Rural Health Policy, HRSA, at [ruralresidency@hrsa.gov](mailto:ruralresidency@hrsa.gov) and 301-443-2203.

#### SUPPLEMENTARY INFORMATION:

*Recipient of the Award:* The University of North Carolina at Chapel Hill.

*Amount of Non-Competitive Award:* One award for \$600,000.

*Project Period:* September 30, 2025, to September 29, 2030.

*Assistance Listing Number:* 93.155.

*Award Instrument:* Cooperative Agreement Supplement.

*Authority:* Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, state	Supplemental award amount
UK6RH32513 .....	University of North Carolina at Chapel Hill .....	Chapel Hill, NC .....	\$600,000

*Justification:* This funding provides a one-time supplement to the University of North Carolina at Chapel Hill through the RRPD-TA Cooperative Agreement. This supplement will allow the University of North Carolina at Chapel Hill to build on past and ongoing projects supported by HRSA to support health care in rural areas by providing additional technical assistance to developing and recently established rural residency programs. The University of North Carolina at Chapel Hill is the recipient of the only award under the RRPD-TA program and has established relationships with rural stakeholders and has longstanding experience developing resources to

support development of rural residency programs. The supplement to the RRPD-TA Cooperative Agreement will allow the University of North Carolina at Chapel Hill to provide additional technical assistance tools and resources to create and sustain new rural residency programs that will expand the rural physician workforce.

**Thomas J. Engels,**

*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the NIH Sleep Disorders Research Advisory Board (SDRAB).

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the

meeting, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Sleep Disorders Research Advisory Board.

*Date:* December 4, 2025.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* The purpose of this meeting is to seek guidance and gather input from the Sleep Disorders Research Advisory Board on research priorities conducted or supported by the Institute; and to continue discussions on the topics for the NIH Sleep Research Plan refresh.

*Place:* National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 407B, Bethesda, MD 20814.

*Meeting Format:* Virtual.

*Contact Person:* Marishka Brown, Ph.D., SDRABExecutive Secretary, Director, NationalCenter on Sleep Disorders Research, National Institutes of Health, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Suite 407B Bethesda, Maryland 20814, 301-435-0199, [ncsdr@nih.gov](mailto:ncsdr@nih.gov).

The event is free and open to the public. Registration is required to attend this meeting. To register, please use <https://events.gcc.teams.microsoft.com/event/e04b4902-7697-417c-bd4e-a94ffe956202@14b77578-9773-42d5-8507-251ca2dc2b06>.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the <https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/sleep-disorders-research>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 14, 2025.

**Denise A. Santeufemio,**

*Supervisory Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-20130 Filed 11-17-25; 8:45 am]

**BILLING CODE 414-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, PAR-22-180: Maximizing Investigators Research Award (MIRA), November 06, 2025, 09:30 a.m. to November 07, 2025, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on August 14, 2025, 90 FR 39205, Doc No. 2025-15430.

This meeting is being amended to change the date from November 6–7, 2025, to November 6, 2025. The meeting is closed to the public.

Dated: September 30, 2025.

**Sterlyn H Gibson,**

*Program Specialist, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### [Docket No. USCG-2010-1066]

#### Recreational Boating Safety Projects, Programs, and Activities Funded Under Provisions of the Infrastructure Investment and Jobs Act; Fiscal Year 2025

##### ACTION: Notice.

**SUMMARY:** The Coast Guard is publishing this notice to satisfy a requirement of the Infrastructure Investment and Jobs Act that requires a detailed accounting of the projects, programs, and activities funded under the national recreational boating safety program provision of the Act to be published annually in the **Federal Register**. This notice specifies the funding amounts the Coast Guard has committed, obligated, or expended

during fiscal year 2025, as of September 30, 2025.

**FOR FURTHER INFORMATION CONTACT:** For questions on this notice please contact Mr. Jeffery Decker, U.S. Coast Guard, Regulations Development Manager, (571) 607-8235 or <mailto:RBSInfo@uscg.mil>.

#### SUPPLEMENTARY INFORMATION:

##### Background and Purpose

Since 1998, Congress has passed a series of laws providing funding for projects, programs, and activities funded under the national recreational boating safety program, which is administered by the U.S. Coast Guard. On November 15, 2021, the Infrastructure Investment and Jobs Act (Pub. L. 117-58, Sec. 28001) set aside funding for Coast Guard administration, which for fiscal year 2025 was \$15.408 million. Of that, not less than \$2.1 million shall be made available to ensure compliance with Chapter 43 of Title 46, U.S. Code, and not more than \$1.5 million is available to conduct by grant or contract a survey of levels of recreational boating participation and related matters in the United States.

These funds are available to the Secretary from the Sport Fish Restoration and Boating Trust Fund (“Trust Fund”) established under 26 U.S.C. 9504(a) for payment of Coast Guard expenses for personnel and activities directly related to coordinating and carrying out the national recreational boating safety program. Amounts made available under this subsection remain available during the two succeeding fiscal years. Any amount that is unexpended or unobligated at the end of the three-year period during which it is available shall be withdrawn by the Secretary and allocated to the States in addition to any other amounts available for allocation in the fiscal year in which they are withdrawn or the following fiscal year.

Use of these funds requires compliance with standard Federal contracting rules with associated lead and processing times resulting in a lag time between available funds and spending.

##### Specific Accounting of Funds

The total amount of funding transferred to the Coast Guard from the Sport Fish Restoration and Boating Trust Fund and committed, obligated, and/or expended during fiscal year 2025 for each project is shown in the chart below.