

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 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.

[FR Doc. 2025-20094 Filed 11-17-25; 8:45 am]

BILLING CODE 4165-15-P

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