

to devices that are appropriately tested in accordance with specific FDA-recognized standards (as outlined in the limitations) and excludes clinical electronic thermometers with telethermographic and continuous temperature measurement functions.

Most contact and non-contact clinical electronic thermometers that are appropriately tested in accordance with specific FDA-recognized standards are well-understood devices; however, FDA

considers premarket notification requirements for clinical thermometers with telethermographic and continuous temperature measurement functions to be necessary to provide a reasonable assurance of safety and effectiveness because such thermometers include newer technology that may require additional testing beyond that specified in FDA-recognized standards and have additional biocompatibility, interoperability, electromagnetic

compatibility, electrical safety, and sterility considerations compared to clinical electronic thermometers without these types of functions.

**IV. Class II Device**

FDA is identifying the following class II device that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in § 880.9:

TABLE 1—CLASS II DEVICES

| 21 CFR section | Device description                    | Product code | Partial exemption limitation   |
|----------------|---------------------------------------|--------------|--|
| 880.2910 ..... | Clinical electronic thermometer ..... | FLL .....    | Exemption is limited to the following: <ol style="list-style-type: none"> <li>1. Device is not a clinical thermometer with telethermography functions;</li> <li>2. Device is not a clinical thermometer with continuous temperature measurement functions; and</li> <li>3. Appropriate analysis and testing (such as outlined in the currently FDA-recognized editions of <i>ISO 80601–2–56 Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement</i>, or <i>ASTM E1965 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature</i>, or <i>ASTM E1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature</i>, or <i>ASTM E1104 Standard Specification for Clinical Thermometer Probe Covers and Sheaths</i>) must validate specifications and performance of the device.</li> </ol> |

FDA will assign new product codes to clinical electronic thermometers with telethermography functions and those with continuous temperature measurement functions in order to ensure that these devices can be identified distinctly from devices that will be exempt subject to the partial limitations under the existing product code (*i.e.*, exempt and non-exempt devices within a device type will have different product codes).

**V. Reference**

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Guidance, “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,” February 19, 1998, available at <https://www.fda.gov/media/72685/download>.

Dated: October 31, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–24290 Filed 11–2–23; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Standardized Work Plan Form for Use With Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than December 4, 2023.

**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 Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–3983.

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

*Information Collection Request Title:* Standardized Work Plan (SWP) Form for Use with Applications to the Bureau of Health Workforce (BHW) Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension

*Abstract:* HRSA’s BHW requires applicants for training and research grants and cooperative agreements to submit work plans via the SWP form.

Information in the SWP describes the timeframes and progress required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement. Applicants use the SWP form when they submit their proposals, and award recipients and Project Officers use the SWP information to assist in monitoring progress once HRSA makes the awards. After awards are made, recipients complete a Quarterly Progress Update (QPU) to provide information to BHW on a quarterly basis on each activity listed in the SWP.

A 60-day notice published in the **Federal Register** on August 25, 2023, vol. 88, No. 164; pp. 58284–85. There were no public comments.

**Need and Proposed Use of the Information:** Information collected by the SWP form and QPUs standardizes and streamlines the data used by HRSA in reviewing applications and monitoring awardees. The form asks applicants to provide a description of the activities or steps the applicant will take to achieve each of the objectives proposed during the entire period of performance. The current standardized format and data submission by

applicants increases efficiency in reviewing, awarding, and monitoring each project.

The QPU is completed via HRSA’s Electronic Handbook system and prompts recipients to report on progress of activities that were submitted using the SWP in the original application. The QPU automatically populates activities from the recipient’s SWP form on a quarterly basis. For each activity listed in the submitted SWP for any particular quarter within the project period, recipients select and submit a single selection response for each activity status from a pull-down menu with five options: Activity is on Schedule, Activity is Complete, Timing is off track, Activity will be missed if action is not taken, and Activity cannot be achieved. Information provided is utilized by the program staff to regularly assess overall progress of program requirements and analyze data in order to monitor award recipient compliance and track progress against proposed targets and goals. Information gathered allows an improved and more efficient method for identifying whether projects’ goals are being advanced or achieved, as set forth in 45 CFR 75.342. Program staff also use information provided over the period of performance to see emerging

trends and to assess whether an award recipient requires technical assistance to address challenges that the award recipient may be experiencing with the implementation of the project. Seeking OMB extension approval comports with the regulatory requirement imposed by 45 CFR 75.206(a), Paperwork clearances.

**Likely Respondents:** Respondents are applicants for, and recipients of, BHW’s research and training grants and cooperative agreements.

**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 annual burden hours |
|--|-----------------------|------------------------------------|-----------------|--|---------------------------|
| Standardized Work Plan (SWP) .....         | 1,000                 | 1                                  | 1,000           | 1.00                                   | 1,000                     |
| Quarterly Progress Update (QPU) Form ..... | 1,000                 | 4                                  | 4,000           | .10                                    | 400                       |
| Total .....                                | <sup>1</sup> 1,000    | .....                              | 5,000           | .....                                  | 1,400                     |

<sup>1</sup> The 1,000 SWP respondents reflects the number of new grant applications submitted annually. The 1,000 QPU respondents reflects the current volume of funded, active grants.

**Maria G. Button,**  
 Director, Executive Secretariat.  
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 BILLING CODE 4165–15–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

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

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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; Advancing Therapeutics II.

**Date:** November 14, 2023.

**Time:** 11:00 a.m. to 1:30 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:** Lystranne Alysia Maynard Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National

Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–4809, [lystranne.maynard-smith@nih.gov](mailto:lystranne.maynard-smith@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 30, 2023.

**Miguelina Perez,**  
 Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24277 Filed 11–2–23; 8:45 am]

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