

time required for this task may range from 5 to 15 minutes; we used the

median, 10 minutes, for the average burden per disclosure (see table 1).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours <sup>2</sup>
54.4(b)—Clinical Investigators .....	13,082	1	13,082	0.17	2,224

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

<sup>2</sup> Numbers have been rounded.

The burden for this information collection request has changed since the last OMB approval. Our estimated burden for the information collection reflects a 298 hour increase. We have adjusted our estimated burden for the information collection to reflect the number of submissions we received in the last few years. Additionally, for products regulated by the Center for Devices and Radiological Health, we now include De Novo requests as a type of application that may rely on clinical studies. Upon review, we have corrected an inadvertent omission regarding the number of BLAs and BLA efficacy supplements received by our Center for Drug Evaluation and Research and used, in part, as a basis for calculating the cumulative burden estimate. We have corrected that error here, as reflected in table 1.

Dated: March 24, 2022.

**Andi Lipstein Fristedt,**

*Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.*

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## 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; Application for Health Center Program Recipients for Deemed Public Health Service Employment With Liability Protections Under the Federal Tort Claims Act, 0906-0035, Revision

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

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has 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 April 29, 2022.

**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 Samantha Miller, the acting HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-9094.

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

*Information Collection Request Title:* Application for Health Center Program Recipients for Deemed Public Health Service Employment with Liability Protections Under the Federal Tort Claims Act (FTCA), OMB No. 0906-0035—Revision.

*Abstract:* Section 224(g)–(n) of the Public Health Service (PHS) Act (42 U.S.C. 233(g)–(n)), as amended, authorizes the "deeming" of entities receiving funds under section 330 of the PHS Act as PHS employees for the purposes of receiving FTCA coverage. The Health Center Program is administered by HRSA's Bureau of Primary Health Care (BPHC). Health centers submit deeming applications annually to BPHC in the prescribed form and manner in order to obtain

deemed PHS employee status for this purpose.

The FTCA Program has a web-based application system, the Electronic Handbooks. These electronic application forms decrease the time and effort required to complete the older, paper-based OMB approved FTCA application forms. The application includes: Contact Information; Section 1: Review of Risk Management Systems; Section 2: Quality Improvement/Quality Assurance; Section 3: Credentialing and Privileging; Section 4: Claims Management; and Section 5: Additional Information, Certification, and Signatures.

HRSA is proposing several changes to the Application for Health Center Program Award Recipients for Deemed PHS Employment with Liability Protections under the FTCA, to be used for health center deeming applications for calendar year 2022 and thereafter, to clarify questions posed and required documentation. Specifically, the Application includes the following proposed changes:

- *Updated application language:* Throughout the application, alternate terminology was utilized to provide greater clarity and specificity. These changes were based on stakeholder feedback and information received from the HRSA Health Center Program Support. These changes are not substantive in nature.

- Some questions were removed from Quality Improvement/Quality Assurance Section, as these questions are similar to information that is also collected in the Risk Management Section. This change is intended to reduce duplicative information collection.

- For the Credentialing and Privileging Section, in this cycle, the application will return to the previous process of submitting a Credentialing List with providers' credentialing and privileging information.

A 60-day notice published in the **Federal Register**, 86 Fed Reg. 72250 (December 21, 2021). There were no public comments.

*Need and Proposed Use of the Information* Deeming applications are required by law and must address certain specific criteria in order for deeming determinations to be issued. The application submissions provide BPHC with the information essential for evaluation of compliance with legal requirements and making a deeming determination under Section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)).

*Likely Respondents:* Respondents include recipients of Health Center

Program funds seeking deemed PHS employee status under Section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)).

*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
FTCA Health Center Program Initial Application .....	35	1	35	2.5	87.5
FTCA Health Center Program Redeeming Application .....	1,125	1	1,125	2.5	2,812.5
Total .....	1,160	.....	1,160	.....	2,900

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.*

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**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be held as a virtual meeting and is open to the public. 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. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

A portion of this 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:* National Advisory Council on Alcohol Abuse and Alcoholism.

*Date:* May 10, 2022.

*Closed:* 11:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Open:* 12:45 p.m. to 5:00 p.m.

*Agenda:* Presentations and other business of the Council.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20817.

*Contact Person:* Abraham P. Bautista, Ph.D., Executive Secretary, National Advisory Council, Director, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 1458, MSC 6902, Bethesda, MD 20892, 301–443–9737, [bautista@mail.nih.gov](mailto:bautista@mail.nih.gov).

*Name of Committee:* National Advisory Council on Alcohol Abuse and Alcoholism, National Cancer Advisory Board, and National Advisory Council on Drug Abuse.

*Date:* May 11, 2022.

*Open:* 11:00 a.m. to 3:00 p.m.

*Agenda:* Presentation of NIAAA, NCI, and NIDA Directors' Update, Scientific Reports, and other topics within the scope of the Collaborative Research on Addiction at NIH (CRAN).

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20817.

*Contact Person:* Abraham P. Bautista, Ph.D., Executive Secretary, National Advisory Council, Director, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 1458, MSC 6902, Bethesda, MD 20892, 301–443–9737, [bautista@mail.nih.gov](mailto:bautista@mail.nih.gov).

Paulette S. Gray, Ph.D., Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 7W444, Bethesda, MD 20892, 240–276–6340, [grayp@dea.nci.nih.gov](mailto:grayp@dea.nci.nih.gov).

Susan Weiss, Ph.D., Director, Division of Extramural Research, National Institute on Drug Abuse, National Institutes of Health, 6001 Executive Boulevard, NSC, Room 5274, Bethesda, MD 20892, 301–443–6487, [sweiss@nida.nih.gov](mailto:sweiss@nida.nih.gov).

Any interested person may file written comments with the committee by forwarding the 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 Institute's/Center's home page: <http://www.niaaa.nih.gov/AboutNIAAA/AdvisoryCouncil/Pages/default.aspx>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)