TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of information collection	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Cognitive Testing	700	1	700	1.41	987
Total	5,575		5,575		3482

[1] May include telephone non-response follow-up in which case the burden will not change.
[2] May include testing of database software, Computer Assisted Personal Interviewing software, or other automated technologies.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–13829 Filed 6–28–23; 8:45 am]

BILLING CODE 4165–15–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; Information Collection Request; Application for Federally Supported Health Centers Assistance Act/Federal Tort Claims Act Particularized Determination of Coverage, 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 submitted an Information Collection Request (ICR), described below, 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 must be received no later than July 31, 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.* 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 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 *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: Application for Federally Supported Health Centers Assistance Act/Federal Tort Claims Act Particularized Determination of Coverage. OMB No. 0906–XXXX–New.

Abstract: Section 224(g)–(n) of the Public Health Service (PHS) Act (42 U.S.C. 233(g)–(n)), as amended, authorizes the Secretary to ''deem'' entities receiving funds under section 330 of the PHS Act (HRSA's Health Center Program) as PHS employees for the purposes of establishing eligibility for liability protections under the Federally Supported Health Centers Assistance Act (FSHCAA) including Federal Tort Claims Act (FTCA) coverage, for covered activities and individuals. Health centers submit deeming applications annually to HRSA's Bureau of Primary Health Care, which administers the Health Center Program and the Health Center FTCA Program, in the prescribed form and manner to obtain deemed PHS employee status for this purpose.

FSHCAA and 42 CFR 6.6(d) authorize FTCA coverage for the provision of medical services to non-health center patients in certain situations. Section 224(g)(1)(C) of the PHS Act and 42 CFR 6.6(d) explain the criteria by which the Secretary will determine whether FSHCAA's liability protections, including FTCA coverage, will extend to the provision of medical care to individuals who are not patients of the health center. 42 CFR 6.6(e) identifies examples that are approvable for FTCA coverage under 42 CFR 6.6(d) and section 224(g)(1)(B)(ii) of the PHS Act if there is compliance with all other coverage requirements under FSHCAA. 42 CFR 6.6(e)(4) provides examples of specific activities that the Department has determined are eligible for FSCHAA's liability protections, including FTCA coverage, without the need for a specific application for a coverage determination. As indicated in 42 CFR 6.6(e)(4), if any element of an activity or arrangement does not fit squarely into the examples listed in 42 CFR 6.6(e), the covered entity should request a particularized determination of coverage. Acts and omissions related to services provided to individuals who are not patients of a covered entity that do not fit squarely within the examples in 42 CFR 6.6(e)(4) will be covered only if the Secretary makes a coverage determination under 42 CFR 6.6(d). The FTCA program uses a web-based application system within HRSA's Electronic Handbooks (EHB) system for deeming applications. These electronic application forms decrease the time and effort required to complete the older, paper-based approved deeming application forms. HRSA is proposing a new paper application that will be transitioned into an electronic application within the EHB system for Particularized Determinations (PD). PDs extend liability protections under FSCHAA, including FTCA coverage, for certain medical services provided to individuals who are not patients of a covered entity. This application will help ensure health centers provide all the necessary information required to make determinations appropriately and efficiently in response to their requests. By including the application within the EHBs, health centers will have access to all information from prior applications and have that information readily available if making future requests. The paper form of the application is an interim solution to support health centers until the electronic application becomes available in the FTCA module of the EHBs. After the electronic application is available in the EHBs, all PD requests will be submitted

electronically, and the paper application will no longer be used for submissions.

A 60-day notice published in the **Federal Register** on March 8, 2023, Vol. 88, No. 45; pp. 14377, received no public comments.

Need and Proposed Use of the Information: PDs of coverage applications are provided in compliance with 42 CFR 6.6 and must address certain specified criteria for coverage determinations to be issued. The application provides the Bureau of Primary Health Care with the information that is essential for evaluation of compliance with legal requirements and making a deeming determination of coverage under 42 CFR 6.6.

Likely Respondents: Respondents include recipients of Health Center Program funds with 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
Application for Federally Supported Health Center Assistance Act (FSHCAA)/Federal Tort Claims Act (FTCA) Particularized Determination	12	1	12	2	24
Total	12	1	12	24	24

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. 2023–13822 Filed 6–28–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Wednesday, July 19, 2023 from 11:00 a.m. until 5:00 p.m., and Thursday, July 20, 2023, from 11:00 a.m. until 5:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website as this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted at least one week prior to the meeting at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Wednesday, July 19, 2023, followed by opening remarks from Julie Kaneshiro, Acting Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with a discussion of IRB effectiveness, topic #4 of the recently published GAO report #GAO–23–104721, Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness. This will be followed by commentary on the FDA draft guidance, Decentralized Clinical Trials for Drugs, Biological Products, and Devices, in addition to discussion of recommendations that address the ethical conduct of decentralized clinical trials in human subjects research more broadly.

Discussion of both topics will continue on July 20, in addition to commentary on the recently released