www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics or *http://www.regulations.gov.*

Dated: July 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16375 Filed 7–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Maternal, Infant, and Early Childhood Home Visiting Program Home Visiting Budget Assistance Tool, OMB No. 0906–0025—Revision

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 announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than September 30, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program Home Visiting Budget Assistance Tool, OMB No. 0906–0025—Revision.

Abstract: HRSA is requesting continued approval and revision to the Home Visiting Budget Assistance Tool (HV-BAT) based on results of the previous pilot test. The tool collects information on standardized cost metrics from programs that deliver home visiting services, as outlined in the HV-BAT. Prior to Fiscal Year (FY) 2021, entities receiving Maternal, Infant, and Early Childhood Home Visiting (MIECHV) formula funds that are states, jurisdictions, territories, and nonprofit awardees may submit cost data using the HV-BAT to HRSA. HRSA will review the data submitted for accuracy and quality control, to test the tool's capacity to support state program functions such as program planning and budgeting, and to collect data to estimate national program costs. Beginning in FY 2021, HRSA will require reporting of HV-BAT data for one-third of awardees in each year for the purpose of informing program planning and budgeting described in awardee submissions of the annual formula funding application.

MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, Tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies (LIAs) in order to provide services to eligible families in at-risk communities.

HRSA revised the intended purpose of the data collection using the HV-BAT. Original clearance under this OMB control number was for pilot testing the reliability of a standardized cost reporting tool among evidence-based home visiting programs. HRSA revised the data collection tool to reflect findings and recommendations from the pilot study to ensure ease of use among LIAs. Changes were made to instructions and definitions based on feedback collected from participants in the pilot study. As this revision seeks to continue collection of comprehensive home visiting cost data for all LIAs in each state, the data can be aggregated to produce state and national cost estimates in addition to supporting procurement activities and sub-recipient monitoring. The burden increased as the pilot study identified a longer average amount of time to complete the tool than was originally estimated.

Need and Proposed Use of the Information: Immediately following OMB clearance, HRSA intends to make the tool available as an optional resource for all awardees. If awardees choose to immediately use the HV-BAT as an optional tool, awardees will be required to submit the data collected with the tool to HRSA. This will allow HRSA to test the feasibility of collecting comprehensive cost data at the state level; estimate national level costs for use in conducting research and analysis of home visiting costs; understand cost variation; assess how comprehensive program cost data can inform other policy priorities, such as innovative financing strategies; review the data to ensure accuracy; and analyze the data for the purpose of federal research.

Beginning in FY 2021, HRSA will require reporting of HV-BAT data for one-third of awardees in each year for the purpose of informing program planning and budgeting described in awardee submissions of the annual formula funding application. HRSA anticipates that one-third of the awardees will participate in this data collection each year and HRSA will identify which third of the awardees will be required to submit HV-BAT data in that year. This process will ease burden on awardees by requiring data collection for each awardee once every 3 years and allowing HRSA to capture a national data set every three years.

Likely Respondents: MIECHV Program awardees (n=19).

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 Information Collection Request 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
Home Visiting Budget Assistance Tool (HV-BAT)	19	13	247	11	2,717
Total	19		247		2,717

Note: The burden estimate assumes that ⅓ of all MIECHV awardees will respond in each year. On average awardees have 13 LIAs (based on 2018 MIECHV program data) that will complete the HV-BAT, and on average it took LIAs 11 hours to complete the HV-BAT in the pilot study (OMB Control No. 0906–0025) of the tool.

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, Division of the Executive Secretariat.

[FR Doc. 2019–16376 Filed 7–31–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 Cancer Institute Special Emphasis Panel; Innovative Molecular Analysis Technologies.

Date: September 19, 2019.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W260, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, 9609 Medical Center Drive, Room 7W260, National Cancer Institute, NIH, Bethesda, MD 20892–9745, (240) 276–5856, *nadeem.khan@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Program Project 1.

Date: September 19–20, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike Rockville, MD 20852.

Contact Person: Clifford W Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Bethesda, MD 20892–8329, 240–276–6343, *schweinfestcw@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Traceback Testing: Outreach for Genetic Counseling of Mutation Carriers.

Date: September 25, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Bethesda, MD 20892–9750, 240–276–6368, *Stoicaa2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–16446 Filed 7–31–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings 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 Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Team-Based Design Review.

Date: October 24, 2019.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; T32 Institutional Training Program Review Meeting.

Date: October 28–29, 2019.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute