TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Section of guidance; recordkeeping activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Sections VI and VII; Charters and SOPs for DMCs | 74 | 1 | 74 | 8 | 592 |
| Section VI.6.C.4.b.; DMC meeting records | 740 | 1 | 740 | 2 | 1,480 |
| Total | | | | | 2,072 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Section of guidance; disclosure activity | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| Section VI.C.4.; DMC reports of meeting minutes to the sponsor | 740 | 2 | 1,480 | 1 | 1,480 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

*Reporting, Recordkeeping, and Third-Party Disclosure Burdens:* Based on our experience and the anticipated increase in DMC use, FDA estimates that there are approximately 1,480 clinical trials with DMCs regulated by the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 740 clinical trials. For the purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials, resulting in an estimated 74 sponsors that are affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends using a DMC, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time is necessary to revise or update them for use for other clinical studies. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial, resulting in the issuance of two DMC reports of meeting minutes (closed and open meeting sessions) to the sponsor. One set of both of the meeting records should be maintained per clinical trial.

Based on a review of the information collection since our last request for OMB approval, our estimated burden for the information collection reflects an overall increase in burden of 1,183 hours and a corresponding increase of 1,794 responses. We attribute this increase generally to an adjustment in respondents based on our experience and the anticipated increase in DMC use. In table 3, since we removed the language in this draft guidance regarding waivers, we removed the ''sponsor notification to the DMC regarding waivers'' task from the burden table, resulting in a decrease of 1 response. In addition, the sections in the draft guidance were changed; therefore, we updated the section numbers in the burden tables in accordance with the draft guidance.

This draft guidance also refers to previously approved FDA collections of information found in FDA regulations. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information pertaining to good clinical practice have been approved under OMB control number 0910–0843. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 54 pertaining to financial disclosure by clinical investigators have been approved under OMB control number 0910–0396.

## III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 6, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–02849 Filed 2–12–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Update to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents; Correction

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

**ACTION:** Notices; correction.

**SUMMARY:** HRSA published documents in the **Federal Register** of October 24,

2023, and January 5, 2024, concerning updates to the Bright Futures Periodicity Schedule as part of the HRSA-supported preventive services guidelines for infants, children, and adolescents. These documents contained minor errors related to updates to two footnotes, including an error in the text of footnote 15 and an error in the description of footnote 21. These minor corrections align with information provided to the public on the Bright Futures web page and referenced by HRSA in the October 24, 2023, **Federal Register** notice that sought public comment on the proposed updates to the Bright Futures Periodicity Schedule. These corrections do not change the clinical recommendations in the Bright Futures Periodicity Schedule or the associated requirement for certain group health plans and health insurance issuers to provide coverage without cost-sharing under section 2713 of the Public Health Service Act.

**FOR FURTHER INFORMATION CONTACT:** Savannah Kidd, M.S. MFT, Sr. Public Health Advisor, Division of Child, Adolescent and Family Health, Maternal and Child Health Bureau, HRSA, telephone: (301) 287–2601, email: *SKidd@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:**

**Correction**

In the **Federal Register** of January 5, 2024, FR Doc. 2024–00024, on page 790, column 3, paragraph 2, correct the text of updated footnote 15 to read as follows: ''A recommended tool to assess use of alcohol, tobacco and nicotine, and marijuana and other substances, including opioids, is available at *http://crafft.org.*'' The document incorrectly omitted the phrase, ''and other substances, including opioids,'' in this sentence.

In the **Federal Register** of January 5, 2024, FR Doc. 2024–00024, on page 790, column 3, paragraph 3, correct the description of the update to footnote 21 to read as follows: ''This updated reference aligns with the Bright Futures recommendation for universal bilirubin screening for all newborn infants between 24 and 48 hours after birth.'' The document incorrectly included the phrase ''between 24 and 28 hours after birth'' in this sentence.

In the **Federal Register** of October 24, 2023, FR Doc. 2023–23396, on page 73035, column 3, paragraph 3, correct the description of the proposed update to footnote 21 to read as follows: ''This reference aligns with the Bright Futures recommendation for universal bilirubin screening for all newborn infants between 24 and 48 hours after birth.'' The document incorrectly included the phrase ''between 24 and 28 hours after birth.''

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2024–02959 Filed 2–12–24; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Advisory Child Health and Human Development Council Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) Implementation Working Group Meeting

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) PRGLAC Implementation Working Group of Council is charged with monitoring and reporting on implementation of the recommendations from the PRGLAC. This includes monitoring and reporting on implementation, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical trials.

**DATES:** The in-person meeting will be held on March 22, 2024, from 8:30 a.m. to 4:30 p.m. EST.

**ADDRESSES:** The in-person meeting will be held on the NIH Campus, 1 Center Dr., Building 31/6C, Room A, Bethesda, MD 20892.

**FOR FURTHER INFORMATION CONTACT:** For information concerning this meeting, Dr. Emma Carpenter, Health Science Policy Analyst, Legislation and Public Policy Branch, Office of Legislation, Public Policy, and Ethics, NICHD, NIH, 6710B Rockledge Drive, Bethesda, MD 20892–7510, *emma.carpenter@nih.gov,* 301–594–2572.

**SUPPLEMENTARY INFORMATION:** This notice is pursuant to 42 U.S.C. 285g. The National Advisory Child Health and Human Development Council Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) Implementation Working Group meeting will be open to the public as a virtual meeting. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed in advance of the meeting.

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: *https://www.nichd.nih.gov/about/advisory,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS).

**Alison N. Cernich,**

*Deputy Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.*

[FR Doc. 2024–02904 Filed 2–12–24; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2023–0672]**

### Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0031

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0031, Plan Approval and Records for Electrical Engineering Regulations—Title 46 CFR Subchapter J; without change.

Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** You may submit comments to the Coast Guard and OIRA on or before March 14, 2024.