

waivers regarding expedited reporting of certain serious events; therefore, FDA has estimated one respondent per year to account for the rare instance a request may be made. 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 to the sponsor. One set of both of the meeting

records should be maintained per clinical trial.

The “Average Burden per Response” and “Average Burden per Recordkeeping” are based on FDA’s experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The “Average Burden per Response” includes the time the respondent would spend reviewing, gathering, and preparing the information to be submitted to the DMC, FDA, or the sponsor. The “Average Burden per

Recordkeeping” includes the time to record, gather, and maintain the information.

The information collection provisions in the guidance for 21 CFR 312.30, 312.32, 312.38, 312.55, and 312.56 have been approved under OMB control number 0910–0014; 21 CFR 314.50 has been approved under OMB control number 0910–0001; and 21 CFR 812.35 and 812.150 have been approved under OMB control number 0910–0078.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Section of guidance/reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
5. Sponsor reporting to FDA on DMC recommendations related to safety.	37	1	37	0.50 (30 minutes) ..	18.5
Total	18.5

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

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
4.1. and 6.4. SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total	1,036

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
4.4.1.2. Sponsor notification to the DMC regarding waivers.	1	1	1	0.25 (15 minutes) ...	0.25
4.4.3.2. DMC reports of meeting minutes to the sponsor.	370	2	740	1	740
Total	740.25

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08963 Filed 4–28–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Commission on Childhood Vaccines; Correction

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

ACTION: Notice; correction.

SUMMARY: HRSA published a document in the **Federal Register** of January 28, 2021, concerning a meeting of the

Advisory Commission on Childhood Vaccines. The document contained incorrect dates. The date of the June 2021 Advisory Commission on Childhood Vaccines (ACCV) meeting has changed. The original date for the June 2021 ACCV meeting was June 3, 2021. The new date for the June 2021 ACCV meeting is June 18, 2021.

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, Rockville, Maryland, 20857, (301) 443–6634; or ACCV@HRSA.gov.

SUPPLEMENTARY INFORMATION: For the latest information regarding the meeting, including its start time and the agenda, please access the ACCV website: <https://www.hrsa.gov/advisory-committees/vaccines/meetings.html>.

Correction

In the **Federal Register** of January 28, 2021, FR Doc. 2021-01879, page 7402, column 3, section 1, paragraph 2, correct the **DATES** caption to read:

DATES: ACCV meetings will be held on:

- March 4, 2021, 10:00 a.m. Eastern Time (ET)—4:00 p.m. ET;
- June 18, 2021, 10:00 a.m. ET—4:00 p.m. ET;
- September 2, 2021, 10:00 a.m. ET—4:00 p.m. ET;
- December 2, 2021, 10:00 a.m. ET—4:00 p.m. ET.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021-08942 Filed 4-28-21; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board Public Teleconference

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB) provides expert advice and guidance on scientific, technical, and other matters of special interest to the Department regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

DATES: The May 26, 2021, public teleconference will include a general discussion of strategic priorities for public health and medical preparedness and a possible vote on recommendations. A more detailed agenda will be available on the NBSB meeting website <https://www.phe.gov/nbsb>.

ADDRESSES: Members of the public may attend the meeting via a toll-free call-in phone number or Web-ex enabled teleconference, which will be posted on <https://www.phe.gov/nbsb>. Members of the public may provide written comments for consideration by the NBSB at any time via email to NBSB@hhs.gov. If such comments are specific to the agenda for the current meeting, please use “NBSB Public Comment for

05/26/2021 in the subject line. Members of the public are encouraged to provide additional comments after the meeting as well.

FOR FURTHER INFORMATION CONTACT:

CAPT Christopher L. Perdue, MD, MPH, Executive Director, National Advisory Committees; NBSB Designated Federal Officer, Washington, DC, Office NBSB@hhs.gov, (202) 401-5837.

SUPPLEMENTARY INFORMATION: The National Biodefense Science Board (NBSB) is authorized under Section 319M of the Public PHS Act, as added by Section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by Section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act. The Board is governed by the Federal Advisory Committee Act (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

Nikki Bratcher-Bowman,

Acting Assistant Secretary for Preparedness and Response.

[FR Doc. 2021-08951 Filed 4-28-21; 8:45 am]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 for Nursing Research.

The meeting will be open to the public as indicated below via videocast. The URL link to this meeting is <https://videocast.nih.gov/watch=41947>. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: National Advisory Council for Nursing Research.

Date: May 18, 2021.

Open: 10:30 a.m. to 3:15 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, One Democracy Plaza, Bethesda, MD 20892, <https://videocast.nih.gov/watch=41947> (Virtual Meeting).

Closed: 3:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, One Democracy Plaza, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan E. Old, Ph.D., Acting Deputy Director, National Institute of Nursing Research, 31 Center Drive, Room 5B05, Bethesda, MD 20892, 301.496.7291, oldse@mail.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: <https://www.ninr.nih.gov/>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: April 23, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-08887 Filed 4-28-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Division of Intramural Research Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the