

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 58 pertaining to good laboratory practice for non-clinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: May 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics Meeting

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/>.

NAME: National Committee on Vital and Health Statistics (NCVHS) Meeting

DATES: Wednesday, June 14, 2023: 10:00 a.m.–4:30 p.m. EDT.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT:

Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to vgh4@cdc.gov; or by telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the NCVHS website <https://ncvhs.hhs.gov/>, where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation, please telephone the CDC Office of Equal Employment Opportunity at (770) 488–3210 as soon as possible.

SUPPLEMENTARY INFORMATION:

Purpose: As outlined in its Charter, the National Committee on Vital and Health Statistics assists and advises the Secretary of HHS on health data, data standards, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),¹ NCVHS advises the Secretary on administrative simplification standards, including those for privacy, security, adoption and implementation of transaction standards, unique identifiers, code sets, and operating rules adopted under the Patient Protection and Affordable Care Act (ACA).²

The purpose of this meeting is to provide a public forum for the Committee to consider what comments it will make on the April 17, 2023, Notice of Proposed Rulemaking (NPRM) “HIPAA Privacy Rule to Support Reproductive Health Care Privacy” which is available at <https://www.federalregister.gov/documents/2023/04/17/2023-07517/hipaa-privacy-rule-to-support-reproductive-health-care-privacy>.

In addition, the Committee will consider what recommendations it will make in response to updated and new operating rules proposed by the Council for Affordable Quality Health Care (CAQH), Committee on Operating Rules for Information Exchange (CORE), to support adopted HIPAA standards, and an updated version of the X12 standard

¹ Public Law 104–191, 110 Stat. 1936 (Aug 21, 1996), available at <https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf>.

² Public Law 111–148, 124 Stat. 119, available at <https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf>.

for claims and electronic remittance advice transactions (Version 8020) proposed by X12. The Committee developed these recommendations in response to formal proposals received from CAQH CORE³ and X12⁴ respectively, informed by a Request for Comment (RFC) and two-day hearing held January 18–19, 2023.⁵ Details on the recent RFC and hearings are available on the Committee's website here: <https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/>.

The Committee will reserve time on the agenda for public comment. Meeting times and topics are subject to change. Please refer to the agenda posted on the NCVHS website for updates: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/>.

Sharon Arnold,

Associate Deputy Assistant Secretary, Office of Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 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: Center for Scientific Review Special Emphasis Panel; Small

³ Letter from CAQH CORE to NCVHS, May 23, 2022: <https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf>.

⁴ Letter from X12 to NCVHS, June 7, 2022: <https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf>.

⁵ See, Subcommittee on Standards, National Committee on Vital and Health Statistics, Hearing on Requests for New and Updated Transaction Standards and Operating Rules, available at <https://ncvhs.hhs.gov/meetings/standards-subcommittee-hearing/>.