

review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information related to the submission of: (1) An investigational new drug application under 21 CFR part 312 have been approved under OMB control number 0910–0014; (2) a new drug application, under 21 CFR part 314 have been approved under OMB control number 0910–0001; (3) a biologics license application (BLA) under 21 CFR part 601 have been approved under OMB control number 0910–0338; and (4) a BLA under section 351(k), under 21 CFR part 601 have been approved under OMB control number 0910–0718. The collections of information regarding current good manufacturing processes for drug products and biological products under 21 CFR part 211 and 21 CFR parts 600, 601, and 610 have been approved under OMB control numbers 0910–0139 and 0910–0338.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–17226 Filed 9–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1955]

E6(R3) Good Clinical Practice; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “E6(R3) Good Clinical Practice.” The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

The guidance includes a principles document and annex 1 and is the precursory guidance to the draft guidance entitled “E6(R3) Good Clinical Practice: Annex 2.” Once complete, the guidance will be composed of a principles document, annex 1, and annex 2. The guidance is intended to outline flexible and modern good clinical practices for conducting clinical trials. Notably, the guidance highlights the importance of quality-by-design, proportionality, and risk-based approaches in conducting clinical trials to ensure safety and reliability of results. The guidance also encourages use of innovative design elements and technology in clinical trials, while avoiding unnecessary complexities. The guidance finalizes the draft guidance of the same title issued on June 7, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on September 9, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2023–D–1955 for “E6(R3) Good Clinical Practice.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling Center for Biologics Evaluation and Research at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Amy Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6334, Silver Spring, MD 20993-0002, 240-402-0992, amy.chi@fda.hhs.gov; Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

Regarding the ICH: Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993-0002, 301-348-1967, Brooke.DalSanto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “E6(R3) Good Clinical Practice.” The guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers

Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to <https://www.ich.org/>).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of June 7, 2023 (88 FR 37257), FDA published a notice announcing the availability of a draft guidance entitled “E6(R3) Good Clinical Practice.” The notice gave interested persons an opportunity to submit comments by September 5, 2023.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in December 2024.

This guidance finalizes the draft guidance issued on June 7, 2023. The guidance offers modernized and agile recommendations for designing and conducting trials efficiently, safely, and innovatively. In response to public comments, the guidance clarifies that technology and design elements are likely to evolve and that the principles of E6(R3) are developed to remain relevant as such advances occur. The guidance stresses proportionality and a focus on the risk to participants and the reliability of the results. Furthermore, the guidance adds clarity to enable different modalities of informed consent (including remote and eConsent) as well as refining language on consent and assent. The guidance also clarifies the responsibilities of the investigators and sponsors regarding delegating clinical trial conduct responsibilities to service providers to reflect the practical application of E6(R3). Lastly, the guidance significantly streamlines and adds clarity to the section on data governance and simplifies the table in

appendix C by providing clarity on the considerations for determining what records are considered essential.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “E6(R3) Good Clinical Practice.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M-25-20, and finds this action to be deregulatory in nature.

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 found in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information under 21 CFR part 312.145 pertaining to good clinical practice have been approved under OMB control number 0910-0843. The collections of information found in 21 CFR parts 50 and 56 pertaining to protection of human subjects, institutional review boards and informed consent have been approved under OMB control number 0910-0130. The collections of information found in 21 CFR part 314 relating to the review of new drug applications have been approved under OMB control number 0910-0001. The collections of information found in 21 CFR part 601 relating to the review of biologic licensing applications have been approved under OMB control number 0910-0338. The collections of information found in 21 CFR part 11 pertaining to electronic records and electronic signatures have been approved under OMB control number 0910-0303. The collections of information found in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910-0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://>

www.regulations.gov, <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>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-17311 Filed 9-8-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Innovations in Nanosystems and Nanotechnology Study Section, October 08, 2025, 09:30 a.m. to October 09, 2025, 06:30 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on August 22, 2025, 90 FR 41091, FR Doc No 2025-16169.

This meeting is being amended to change the meeting start time from 9:30 a.m. to 9:00 a.m. The date and location remain the same. The meeting is closed to the public.

Dated: September 4, 2025.

Denise M. Santeufemio,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-17280 Filed 9-8-25; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the NIH Clinical Center Research Hospital Board.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting

can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

Name of Committee: NIH Clinical Center Research Hospital Board.

Date: October 17, 2025.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: NIH and Clinical Center (CC) Leadership Announcements, CC Acting Chief Executive Officer (CEO) Update of Recent Activities and Organizational Priorities, and Other Business of the Clinical Center Research Hospital Board (CCRHB).

Place: National Institutes of Health, Building 31, Conference Room 6C02 A & B, 9000 Rockville Pike, Bethesda, MD 20892 (In-Person and Virtual).

Contact Persons: Patricia Piringner, RN, MSN (C), National Institutes of Health Clinical Center, 10 Center Drive, Bethesda, MD 20892, ppiringner@cc.nih.gov, (301) 402-2435, (202) 460-7542 (direct).

Natascha Pointer, Management Analyst, Executive Assistant to Dr. Gilman, Office of the Chief Executive Officer, National Institutes of Health Clinical Center, 10 Center Drive, Bethesda, MD 20892, npointer@cc.nih.gov, (301) 496-4114, (301) 402-2434 (direct).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person(s) 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.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the CCRHB website: <https://www.ccrhb.od.nih.gov/> where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: September 5, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025-17288 Filed 9-8-25; 8:45 am]

BILLING CODE 4140-01-P

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: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: October 9-10, 2025.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Irina V. Nesmelova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-6496, irina.nesmelova@nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Behavioral Neuroendocrinology, Neuroimmunology, Rhythms, and Sleep Study Section.

Date: October 14-15, 2025.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Simon Peter Peron, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 1009K, Bethesda, MD 20892, (301) 594-6236, peronsp@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: October 14-15, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.