MD 20993–0002, 301–348–1967, *Brooke.DalSanto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''E20 Adaptive Designs for Clinical Trials.'' The draft guidance was prepared under the auspices of ICH.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 the 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 June 2025, the ICH Assembly endorsed the draft guideline entitled ''E20 Adaptive Designs for Clinical Trials'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance provides transparent and harmonized recommendations for the planning, conduct, analysis, and interpretation of clinical trials with an adaptive design that aim to confirm the efficacy and support the benefit-risk assessment of a treatment. For the purpose of this draft guidance, an *adaptive design* is defined as a clinical trial design that allows for prospectively planned modifications to one or more aspects of the trial based on interim analysis of accumulating data from participants in the trial. Adaptive designs offer a variety of advantages and challenges. This draft guidance emphasizes principles that are critical for ensuring clinical trials produce reliable and interpretable results and that involve specific considerations with use of an adaptive design. While this draft guidance primarily focuses on confirmatory clinical trials, the principles are relevant to all clinical development phases.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''E20 Adaptive Designs for Clinical Trials.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 relating to the protection of human subjects, informed consent, and institutional review boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 312 relating to submission of investigational new drug applications, including efficient approaches to clinical trial design, study protocols, and the operation of data monitoring committees, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to submission of biologic license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 812 relating to investigational device exemption applications have been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain the draft 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. 2025–18897 Filed 9–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–0198]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed Information Collection Request (ICR) for public comment.

DATES: Comments on the ICR must be received on or before November 28, 2025.

ADDRESSES: Submit your comments to Sheila Garrity, Director, Office of Research Integrity *ORI_Public_Comments@hhs.gov*.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0937–0198–60D and project title for reference, to Sheila Garrity, Director, Office of Research Integrity *ORI_Public_Comments@hhs.gov*.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: Public Health Service Policies on Research Misconduct (42 CFR part 93).

Type of Collection: Revision.

OMB No. OS–0937–0198.

Abstract: The Office of Research Integrity (ORI) is seeking a revision of its collection instruments to reflect updates in the Public Health Service Policies on Research Misconduct (42 CFR part 93) published on September 17, 2024. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form PHS–6349 is to provide data on the amount of research misconduct activity (*e.g.,* allegations of research misconduct and assessments, inquiries, and/or investigations of such allegations) occurring at institutions conducting PHS-supported research. These data enable the ORI to monitor institutional compliance with the PHS regulation. Form PHS–6349 has undergone minor revisions, but its function is unchanged. The purpose of the Assurance of Compliance by Sub-Award Recipients form PHS–6315 establishes an assurance of compliance for a sub-awardee institution. Form PHS–6315 is being discontinued. In its place, ORI developed a new form, the Research Integrity Assurance Establishment form PHS–7091. This form allows all institutions subject to 42 CFR part 93 to establish an assurance with ORI, regardless of sub-awardee status. Additionally, ORI developed a second new form, the Institutional Record Transmittal form PHS–7092, which accounts for the varied types of information collection that can occur during the course of institutional research misconduct proceedings. ORI continues to utilize the Small Institution Statement to assist small institutions as part of the assurance process, which has been updated to reflect new regulatory language. This statement is an addendum that can be included with form PHS–6349 and PHS–7091, where applicable.

Need and Proposed Use: The information is needed to fulfill section 493 of the Public Health Service Act (42 U.S.C. 289b), which requires assurances from institutions that apply for financial assistance under the Public Health Service Act for any project or program that involves the conduct of biomedical or behavior research. In addition, the information is also required to fulfill the assurance and annual reporting requirements of 42 CFR part 93. ORI uses the information to monitor institutional compliance with the regulation. Lastly, the information may be used to respond to congressional requests for information to prevent the misuse of Federal funds and to protect the public interest.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Research Integrity Assurance and Annual Report on Possible Research Misconduct (PHS–6349).	Awardee Institutions	6,619	1	.1666	1,103
Research Integrity Assurance Establishment form (PHS–7091).	New Awardee Institutions	428	1	.1666	71
Institutional Record Transmittal form (PHS–7092).	Institutions	230	1	.1666	38
Total		7,277	3		1,212

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2025–18909 Filed 9–29–25; 8:45 am]

BILLING CODE 4150–28–P

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 Center for Scientific Review Special Emphasis Panel, RFA–AI–24–080 Broad Spectrum Products Against Multiple Neurotoxin Botulinum Serotypes (R61/R33 Clinical Trial Not Allowed). November 14, 2025, 10:00 a.m. to November 14, 2025, 05:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 23, 2025, 90 FR 45775, Doc No. 2025–18347

This meeting is being amended to change the date from November 14, 2025, to December 2, 2025. The meeting is closed to the public.

Dated: September 26, 2025.

Denise M. Santeufemio,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–19026 Filed 9–29–25; 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,