

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.
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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 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. Santereumio,
Program Analyst, Office of Federal Advisory Committee Policy.

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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,