



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 **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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 USC 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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