



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0937-0198-30D]

Agency Information Collection Request. 30-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, submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, Director, Office of Research Integrity, ORI_Public_Comments@hhs.gov. When submitting comments or requesting information, please include the document identifier 0937-0198-30D and project title for reference.

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. 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 behavioral 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 misuse of Federal funds and to protect the public interest.

In accordance with 5 CFR Part § 1320.8(d), 60-day notice was published on September 30, 2025, in the Federal Register Volume 90, Number 187, Pages 46901-46902 to solicit public comment on the revision of form PHS-6349, the new collection instruments (the Institutional Record Transmittal form PHS-7092 and the Research Integrity Assurance Establishment form PHS-7091), and the discontinuance of PHS-6315 reflecting changes in the 2024 Final Rule, 42 CFR Part 93. There was one public comment. This comment did not change ORI’s burden estimates and without passion or prejudice, ORI is proceeding with this 30-day comment period regarding three-year OMB approval for its revised and new collection instruments. Regarding the frequency of response for the collection instrument, form PHS-6349 must be submitted by institutions conducting PHS-supported research on an annual basis; form PHS-7091 must be submitted by institutions to ORI once when seeking an ORI assurance for the first time; PHS-7091 must be submitted to ORI by an institution on a case-by-case basis at the conclusion of institutional research misconduct proceedings.

Estimated Annualized Burden Hour Table

| Forms (If necessary) | Respondents (If necessary) | Number of Respondents | Number of Responses per Respondents | Average Burden per Response (minutes) | Total Burden Hours |
|---|-----------------------------------|------------------------------|--|--|---------------------------|
| Research Integrity Assurance and Annual Report on Possible Research Misconduct (PHS-6349) | Awardee Institutions | 6,619 | 1 | 10/60 | 1,103 |

| | | | | | |
|--|--------------------------|-------------|---|-------|--------------|
| Research Integrity Assurance Establishment form (PHS-7091) | New Awardee Institutions | 428 | 1 | 10/60 | 71 |
| Institutional Record Transmittal form (PHS-7092) | Institutions | 230 | 1 | 10/60 | 38 |
| | | | | | |
| Total | | <i>7277</i> | | | 1,212 |

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

[FR Doc. 2025-22153 Filed: 12/5/2025 8:45 am; Publication Date: 12/8/2025]