Supporting Statement

Revision Request for 0937-0198 for Public Health Service Policies on Research Misconduct (42 CFR Part 93) Institutional Record Transmittal form, Research Integrity Assurance Establishment form, and Research Integrity Assurance and Annual Report on Possible Research Misconduct form.

Background

This is a request for the Office of Management and Budget (OMB) to approve the revision of information collection requirements the Office of the Assistant Secretary for Health (OASH) Office of Research Integrity (ORI) conducts. This request involves the approval of two new forms: the Institutional Record Transmittal form (PHS-7092) and the Research Integrity Assurance Establishment form (PHS-7091). This request also involves the revision of the Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349) and discontinuance of the Assurance of Compliance by Sub-Award Recipients form (PHS-6315).

As a routine course of operation, ORI provides regulatory oversight of institutional activities as they relate to addressing allegations of research misconduct involving research funded by the Public Health Service (PHS). When allegations of research misconduct emerge, regulated institutions have reporting, recordkeeping, and third-party disclosure requirements, which vary on a case-by-case basis. ORI also monitors compliance with the PHS research misconduct regulations by reviewing institutional assurances, which are a prerequisite for receiving PHS funds.

On September 17, 2024, the Federal Register published the final rule for Public Health Service Policies on Research Misconduct 42 CFR Part 93. This regulation replaces ORI's 2005 regulation by the same name. ORI did not concurrently develop the Paperwork Reduction Act (PRA) information request during the Notice of Proposed Rulemaking (NPRM) submission in 2023 as part of its development of the 2024 final rule. ORI is now seeking OMB approval of two new forms and revision of a third form in order to come into PRA compliance.

ORI is seeking OMB approval for the proposed Institutional Record Transmittal form, which allows institutions conducting PHS-supported research to attest that they have followed the regulations in 42 CFR Part 93 involving all reporting, recordkeeping, and third-party disclosure requirements that may occur during institutional research misconduct proceedings. This form would accompany the institutional record that Research Integrity Officers (RIOs) or other institutional officials send to ORI electronically in the course of research misconduct proceedings. ORI has developed administrative burden estimates for these information collection processes during the OMB clearance process for the final rule. These institutional reporting, recordkeeping, and third-party disclosure requirements covered by the Institutional Record Transmittal form (PHS-7092) include:

- Documenting subsequent use exceptions, 42 CFR § 93.104(1)(ii)

- Providing respondents (those alleged to have committed research misconduct) access to sequestered research records, 42 CFR § 93.305(b)
- Maintenance of sequestered research records and other evidence, 42 CFR § 93.305(c)
- Notifying ORI of special circumstances during misconduct proceedings, 42 CFR § 93.305(g)
- Documenting assessments, 42 CFR § 93.306(c)(2)(i)
- Sequestration of evidence at the initiation of an inquiry, 42 CFR § 93.306(c)(2)(ii)
- Documenting why an institution did not conduct an inquiry, 42 CFR § 93.306(c)(3)
- Sequestration of records during an inquiry, 42 CFR § 93.307(d)
- Providing notice to respondent at the initiation of an inquiry, 42 CFR § 93.308(a)
- Providing ORI an inquiry report at the initiation of an investigation, 42 CFR § 93.309(a)
- Documenting why an institution did not conduct an investigation, 42 CFR § 93.309(b)
- Notifying ORI of special circumstances during an inquiry, 42 CFR § 93.309(c)
- Notifying ORI of the initiation of an investigation, 42 CFR § 93.310(b)
- Requesting extensions from ORI for investigations, 42 CFR § 93.310(b)
- Providing progress reports to ORI during extensions, 42 CFR § 93.310(c)
- Notifying respondents of the initiation of an investigation, 42 CFR § 93.310(d)
- Conducting, recording, and transcribing interviews, 42 CFR § 93.310(g)
- Making transcripts available to interviewees for correction, 42 CFR § 93.310(g)(3)
- Providing respondents with transcripts of interviews, 42 CFR § 93.310(g)(5)
- Pursuing leads during an investigation, 42 CFR § 93.310(j)
- Providing respondents access to the investigation report for comment, 42 CFR § 93.312(a)
- Producing the final investigation report, 42 CFR § 93.313
- Notifying ORI of appeals, 42 CFR § 93.315(a)
- Transferring the institutional record to ORI at the conclusion of an appeal, 42 CFR § 93.315(b)
- Providing ORI a record of an appeal, 42 CFR § 93.315(c)
- Producing a letter from an Institutional Deciding Official, 42 CFR § 93.316
- Notifying ORI of a settlement with respondent, 42 CFR § 93.317(a)
- Producing an admission statement (done by respondent), 42 CFR § 93.317(b)
- Producing a statement of admission on addressing scope of misconduct (done by institution), 42 CFR § 93.317(b)
- Maintenance of institutional record and all sequestered evidence, 42 CFR § 93.318(a)

This revision request also involves the proposed Research Integrity Assurance Establishment form (PHS-7091). The 2024 final rule updated 42 CFR Part 93 sections on compliance (§ 93.300-304) and treats all PHS awardees the same; all are required to seek and maintain a research integrity assurance. The previous 2005 regulation treated awardees and sub-awardees differently; only the primary awardee was required to seek and maintain a research integrity assurance. Therefore, ORI has developed the new Research Integrity Assurance Establishment form (PHS-7091) as a general intake form for all new awardees that have not previously sought an ORI assurance. The function of this form is for institutions to attest that they will abide by the regulations in 42 CFR Part 93 to address research misconduct allegations and submit written

policies and procedures for ORI verification. Because there is no longer a need to track sub-awardees per the 2024 final rule, we request that the Assurance of Compliance by Sub-Award Recipients form (PHS-6315) be discontinued.

Additionally, this request involves the revision of the Institutional Assurance and Annual Report on Possible Research Misconduct form (PHS-6349). Revisions to this form primarily involve updates to the language reflected in the 2024 final rule. The form also adds information collection on institutional assessments, which is an initial part of research misconduct proceedings identified in the updated regulation. The OMB approval number (09370198) for ORI's current forms (PHS-6349 and PHS-6315), under the Public Health Service Policies on Research Misconduct, expires on August 31, 2026.

A. Justification

1. Need and Legal Basis

Section 493 of the Public Health Service (PHS) Act, as amended by Pub. L. 99158, the Health Research Extension Act of 1985, provides that the Secretary by regulation shall require that each entity that applies for a grant, contract or cooperative agreement for any project or program involving the conduct of PHS-funded biomedical or behavioral research shall: (1) submit an approved assurance that the institution has established written policies and procedures for inquiring into and investigating allegations of research misconduct, as required by 42 CFR Part 93; and (2) report any investigation of alleged research misconduct.

The subsequent regulation, 42 CFR Part 50, Subpart A, which was published in 1989, stated that: "An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe." A similar requirement is included in the current regulation, 42 CFR Part 93. Also in 1989, the Assistant Secretary for Health created the Office of Scientific Integrity and the Office of Scientific Integrity Review.

Section 493 of the PHS Act was further amended by the NIH Revitalization Act of 1993, which mandated the creation of the Office of Research Integrity as an independent entity within the Department of Health and Human Services (HHS). In June 2005, 42 CFR Part 50, Subpart A was superseded by the Public Health Service Policies on Research Misconduct (42 CFR Part 93), which details the responsibilities of HHS, ORI, and institutions in addressing allegations of research misconduct involving PHS-supported research.

42 CFR Part 93 provides ORI the authority to seek and collect documentation of institutional activities to address allegations of research misconduct involving PHS-funded research. These activities include ORI's collection of the institutional record created during research misconduct allegation proceedings, which include but are not limited to documents (whether in hard copy or electronic form), information, tangible items, and testimony. ORI released an updated version of 42 CFR Part 93 on September 16, 2024, based on two decades of experience working with the regulated community on research misconduct allegations.

In the course of publishing the final rule, ORI is seeking OMB approval for these required reporting and recordkeeping activities, which enable ORI to provide regulatory oversight for HHS and help safeguard public funds by ensuring the integrity of PHS-funded research. To accomplish this task, ORI developed the Institutional Record Transmittal form (PHS-7092). This information collection instrument is designed to broadly capture the reporting, recordkeeping, and third-party disclosure requirements that can occur during institutional research misconduct proceedings, which vary on a case-by-case basis.

Because the updated 42 CFR Part 93 treats all PHS awardees the same regardless of whether they are a primary or sub-awardee, ORI is also seeking OMB approval for the proposed Research Integrity Assurance Establishment form (PHS-7091), which ensures that any institution receiving PHS support for research provides HHS with an assurance of compliance in accordance with 42 CFR Part 93. Additionally, ORI is seeking OMB approval to revise the Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349) to reflect revised regulatory language and reporting requirements.

2. Information Users

The data acquired through the proposed Institutional Record Transmittal form (PHS-7092) would be used by ORI in the course of providing oversight or responding directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter consistent with 42 CFR Part 93. The data gathered from the proposed Research Integrity Assurance Establishment form (PHS-7091) allows ORI and PHS agencies to verify the eligibility of institutions and organizations to receive PHS funds for research, research training, and research-related activities. To be eligible for funding, institutions and organizations must first submit an institutional assurance and then keep their assurance active by filing their Annual Report (PHS-6349) with ORI. The combination of institutional assurances and PHS-6349 are used by ORI to monitor adherence to the regulation by institutions and organizations. Aggregate data on the reported misconduct activity may also be presented to the research community through various channels (e.g., the ORI Annual Report, ORI website, and conferences and workshops).

3. Improved Information Technology

Beginning with the CY 2000 Annual Report, the burden on awardee institutions and ORI was substantially reduced by the introduction of electronic submission as an option for submitting the Institutional Assurance and Annual Report on Possible Research Misconduct form (PHS-6349). All awardee institutions now can electronically complete and file PHS-6349 with ORI. This takes approximately 10 minutes. The availability of electronic submissions gives ORI real-time access to the database, which has enhanced database accuracy. Institutions may update their information throughout the year so that whenever ORI accesses the data, it is the most current information available. This also has substantially reduced the time required for ORI to keep the assurance database up to date. ORI sends email messages to provide advance notice and ongoing reminders about submitting the Annual Report. The availability of electronic submission for the Annual Report has nearly eliminated the use of paper-based mail.

For new assurances, the Research Integrity Assurance Establishment form (PHS-7091) is designed to reduce burden by providing a brief attestation of assurance of compliance with 42 CFR Part 93. This proposed form would be submitted electronically using the same systems as PHS-6349.

ORI also designed the proposed Institutional Record Transmittal form (PHS-7092) to limit public burden by reducing documentation of all reporting, recordkeeping, and third-party disclosure requirements to an attestation that the RIO or other institutional official in charge of research misconduct proceedings has submitted the complete institutional record in accordance with 42 CFR Part 93. ORI will also receive this form electronically in an ORI system institutions already use to submit reports and accompanying institutional records. This streamlined approach allows users flexibility because research misconduct proceedings (and the accompanying institutional record) vary on a case-by-case basis.

4. Duplication of Similar Information

Similar data are not collected by ORI or any other organization.

5. Small Businesses

Section 493 of the Public Health Service Act provides that, by regulation, the Secretary shall require each entity to develop an administrative process for investigating and reporting incidents of misconduct. Under 42 CFR Part 93, small institutions must file an Annual Report (PHS-6349) but may include a Small Institution Statement in lieu of writing extensive research misconduct policies and procedures. Under the Small Institution Statement provision, ORI and the small institution develop a process for responding to allegations, and the small institution is required to inform ORI of any allegation of research misconduct it receives. This provision is intended to address the actual or apparent conflicts of interest small institutions frequently face. The burden on a small institution for completing and submitting the Small Institution Statement is not significant.

When applying for an ORI assurance for the first time, small institutions can submit the Small Institution Statement as an addendum alongside the proposed Research Integrity Assurance Establishment form (PHS-7091). ORI has revised the language in its Small Institution Statement in accordance with the updated regulation, but its function remains unchanged.

In regard to the regulation's required reporting and recordkeeping activities, the most significant burden that could fall on an entity filing a Small Institution Statement is in addressing allegations of research misconduct, which would include obtaining all research records and other evidence when there is an allegation of research misconduct, engaging persons to handle the process for addressing the allegations of research misconduct, and submitting reports and evidence to support the small institution's results and conclusions of research misconduct proceedings. This status quo is unchanged from the previous regulation, and ORI continues to offer technical assistance for small institutions when they receive research misconduct allegations.

6. Less Frequent Collection

Under both the previous and revised 42 CFR Part 93, ORI collects information about institutional research misconduct proceedings as needed for regulatory oversight. This information is not collected at regular intervals but rather as the proceedings of research misconduct allegations develop on a case-by-case basis. When institutions complete proceedings, they will submit the proposed Institutional Record Transmittal form (PHS-7092) to ORI along with the materials institutions collected for ORI's regulatory oversight, which constitutes the institutional record for that case.

The information collected annually through Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349) cannot be collected less frequently because the information is necessary for maintaining an accurate assurance database. Information stored in ORI's assurance database is used to determine if an institution has an active research integrity assurance on file with ORI, which is a prerequisite for receiving PHS funding. ORI also uses the information provided on PHS-6349 to annually monitor compliance with the regulatory requirement to report the opening of all investigations into allegations of potential research misconduct. In addition, PHS-6349 captures other institutional research misconduct proceedings that lead to investigations including the receipt of allegations, assessments, and inquiries. When filing the PHS-6349, institutions identify the institutional official responsible for implementing research misconduct policies and procedures in adherence with 42 CFR Part 93. ORI uses this information when referring allegations to institutions and communicating about research misconduct education and prevention activities. Less frequent information collection is not only prohibited by 42 CFR Part 93 but would also be problematic and could reduce the accuracy of the information submitted in the reports.

The information collected through the Research Integrity Assurance Establishment form (PHS-7091) cannot be collected less frequently because it is required by 42 CFR Part 93. This information is also necessary for maintaining an accurate research integrity assurance database. PHS-7091 enables ORI to determine if an institution has a valid assurance and is eligible to receive PHS funding. When filing PHS-7091, institutions also identify the institutional official responsible for implementing relevant parts of 42 CFR Part 93. Less frequent information collection would be problematic as an ORI assurance is necessary to receive PHS funding.

7. Special Circumstances

Regulations are consistent with 5 CFR 1320.5.

8. Federal Register Notice

The updated 42 CFR Part 93 was published in the Federal Register on September 16, 2024. 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 proceeded with a 30-day comment period regarding its revised and new collection instruments.

Subsequently, a 30-day notice was published on December 8, 2025, in the Federal Register Volume 90, Number 233, Page 56775-56776 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.

9. Payment/Gift to Respondent

No payments or gifts were or will be given to Respondent.

10. Confidentiality

ORI maintains confidentiality within the limits of the law, which would include the use of the proposed Institutional Record Transmittal form. Regarding the assurance and compliance forms, ORI does not provide any promises of confidentiality to the respondents.

11. Sensitive Questions

ORI does not require institutions to report sensitive information on the proposed Institutional Record Transmittal form (PHS-7092) itself. Institutions are only required to verify that they have completed the recordkeeping and reporting requirements consistent with relevant activities detailed in 42 CFR Part 93. However, this form accompanies the submission of the institutional record of research misconduct proceedings, and the institutional record itself may contain sensitive information as required by the regulation, which varies on a case-by-case basis. This sensitive information is not made public except for what is required by law.

The Research Integrity Assurance Establishment form (PHS-7091) and Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349) collect data on the institutional policies and procedures for addressing research misconduct allegations. No sensitive information is collected on the persons involved in the allegations. The information collected in both forms includes name and business contact information for certain institutional officials.

12. Burden Estimate (Total Hours and Wages)

12 (A) Estimated Annualized Burden Table for Required Reporting, Recordkeeping, and Third-Party Disclosure Activities

Forms (If Necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
Recordkeeping	Institutions	230	1	680	156,400
Reporting	Institutions	230	1	163	37,490
Third-Party Disclosure	Institutions	230	1	118	27,140
Institutional Record Transmittal Form (PHS-7092)	Institutions	230	1	10/60	38
Research Integrity Assurance Establishment form (PHS-7091)	New Awardee Institutions	428	1	10/60	71
Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349)	Institutions	6,619	1	10/60	1,103
Total					222,243

The estimated burden hours per response for institutions completing the Institutional Record Transmittal form is 10 minutes per online submission. The estimated burden hours per response for institutions completing the Research Integrity Assurance Establishment form is 10 minutes per online submission. The estimated burden hours per response for institutions completing the Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349) is 10 minutes per online submission.

12.(B) Estimated Annualized Cost to Respondents

Forms (If necessary)	Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Recordkeeping	Institutions	156,400	$111.00	$17,360,400
Reporting	Institutions	37,490	$111.00	$4,161,390
Third-Party Disclosure	Institutions	27,140	$111.00	$3,012,540
Institutional Record Transmittal form	Institutions	38	$111.00	$4,218.00

(PHS-7092)				
Research Integrity Assurance Establishment form (PHS-7091)	Institutions	71	$111.00	$7,881.00
Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349)	Awardee Institutions	1,103	$111.00	$122,433.00
Total				$24,668,973

13. Capital Costs

Regarding the Research Integrity Assurance Establishment form (PHS-7091) and the Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349), the data can be collected with ORI systems that the institutions and organizations are already using to submit this information. Regarding required reporting, recordkeeping, and third-party disclosure activities that occur during the course of research misconduct proceedings and constitute the institutional record (verified by Institutional Record Transmittal form PHS-7092) the data can also be collected with ORI systems that the institutions and organizations are already using to submit this information. There is no start-up cost associated with any of these instruments.

14. Cost to Federal Government

Regarding required reporting, recordkeeping, and third-party activities, there is no additional cost to the government as this activity is limited to research institutions.

Regarding the Institutional Record Transmittal form (PHS-7092), we identify a first-year cost to the federal government associated with preparing this information collection request for OMB. This request took approximately 100 hours of a person at the GS-11 level and 25 hours spent by an individual at the GS-15 level. Adopting hourly basic rates for the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA for 2025, we calculate a combined annual cost of $6,062. We do not identify any ongoing costs associated with this information collection request should it be approved. Third-party recordkeeping and collection costs associated with institutional misconduct proceedings do not create any additional costs for the federal government. Regarding the Research Integrity Assurance Establishment form and the Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349), the estimate of the annual cost to the federal government for the information collection requirement of these forms is approximately 50% of one person year at a GS-12 level. Adopting the annual rate for the same locality, we calculate an annual cost of $50,701. The first-year cost

is $56,192 total.

15. Program or Burden Changes

Regarding required reporting, recordkeeping, and third-party activities, the estimate of burden hours per person per year is 961 (=221,030/230) hours for each research misconduct case. This calculation was done by adding our updated burden totals for recordkeeping (156,400), reporting (37,490), and third-party disclosure (27,140) divided by 230 cases, which was our most recent total of active research misconduct cases. Although 42 CFR Part 93 revises and clarifies institutional research misconduct proceedings in which ORI has oversight, institutional activities (and associated burden) as they relate to addressing allegations of research misconduct have not fundamentally changed since the original publication of 42 CFR Part 93 in 2005. In the past two decades and moving forward, institutions conducting PHS-supported research may continue to assess research misconduct allegations, conduct inquiries and investigations, sequester and analyze evidence, conduct interviews, convene committees, make determinations, and report to ORI on a case-by-case basis; however, these burden hours were not calculated in ORI's previous PRA clearance requests.

Regarding the Institutional Record Transmittal form, the estimate of burden hours per person per year is 10 minutes for each research misconduct case. Regarding the Research Integrity Assurance Establishment form, the estimate of total burden hours is 10 minutes per new awardee institution. Because the updated 42 CFR Part 93 necessitates both new and revised collection instruments, this PRA clearance request is classified as a program change.

16. Publication and Tabulation Dates

Regarding the publication of data on ORI's current and proposed forms, the information collected from the Research Integrity Assurance Establishment form and the Research Integrity Assurance and Annual Report on Possible Research Misconduct form (PHS-6349) will be analyzed internally and only used for reporting to authorized administrative officials and for responding to congressional and public inquiries. In addition, ORI may publish the information in aggregate form in the ORI Annual Report and on the ORI website. ORI may share an institutional official's business contact information with other institutional officials, if requested.

Regarding required recordkeeping activities, ORI may disclose information to other persons, as permitted under the Privacy Act, 5 U.S.C. 552a, for the purpose of providing or obtaining information about research misconduct and for ORI's system of records notice for research misconduct proceedings. ORI may also disclose or publish a notice regarding settlements, ORI findings of research misconduct, and HHS administrative actions. ORI may release or withhold information as permitted by the Privacy Act and the Freedom of Information Act, 5 U.S.C. 552. Regarding the Institutional Record Transmittal form, the information is for administrative purposes only. ORI would not disclose it to other persons.

ORI is seeking a three-year clearance for the use of PHS-6349, PHS-7091, and PHS-7092 in order to maintain regular operations of the office. The revised 42 CFR Part 93 is applicable to all

PHS-funded institutions on January 1, 2026, and information collection must begin using PHS-6349, PHS-7091, and PHS-7092 on this date.

17. Expiration Date will be visible.

18. Certification Statement

There are no exceptions.

B. Collection of Information Employing Statistical Methods

ORI is not utilizing statistical methods to collect information.