GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Implementing the Revised Regulation

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Research Integrity (ORI)
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This guidance document is provided by the Office of Research Integrity (ORI) to assist entities that apply for or receive Public Health Service (PHS) funding for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training. It addresses implementation of the revised Public Health Service Policies on Research Misconduct regulation at 42 CFR Part 93 (2024). This guidance document does not create or confer rights for or on any person and does not operate to bind ORI, the Department of Health and Human Services, or the public. It also does not guarantee that ORI will find an institution compliant with 42 CFR Part 93. In case of any conflict between this document and 42 CFR Part 93, the regulation will prevail.

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Overview

In 2024, the U.S. Department of Health and Human Services (HHS) revised its Public Health Service (PHS) Policies on Research Misconduct regulation (42 CFR Part 93), replacing the 2005 version of the regulation. Part 93 applies to the HHS Office of Research Integrity (ORI) and all institutions that apply for or receive PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.[1] Institutions must comply with the requirements of the revised regulation starting on January 1, 2026. This guidance document explains when institutions should follow the revised regulation or the 2005 regulation for ongoing and new research misconduct proceedings, and when institutions must submit written policies and procedures that comply with the revised regulation.

Managing Ongoing Proceedings and New Allegations

The following information is intended to help institutions understand when to follow the revised regulation or the 2005 regulation for a research misconduct proceeding.

1. For **allegations of research misconduct received by an institution on or after January 1, 2026**, the institution must follow the revised regulation.[2]

2. For **allegations of research misconduct received by an institution before January 1, 2026,** there are two scenarios.

    a) **Default to 2005 Regulation:** The institution must follow the 2005 regulation, even if the proceeding continues beyond January 1, 2026, unless both the institution and respondent elect in writing to follow the revised regulation.[3]

    b) **Optional Use of Revised Regulation by Written Election:** The institution may follow the revised regulation, only if both the institution and respondent elect in writing to do so.[4]

    For allegations of research misconduct received by an institution before January 1, 2026, ORI recommends noting in the inquiry report and investigation report whether the institution is applying the 2005 regulation or the updated 2024 regulation to the proceeding. If the institution is applying the updated regulation, it must include the written election in the Institutional Record.[5]

The institution should ensure it is applying the written policies and procedures that correspond to the version of the regulation the proceeding is following.

General questions about applicability of the revised and 2005 regulations may be directed to AskORI@hhs.gov.

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[1] 42 CFR § 93.102(a).
[2] § 93.75(a)
[3] § 93.75(b)
[4] *Id*.
[5] § 93.220(a)

Compliance and Assurances

ORI continues to require active assurances from all institutions that apply for or receive PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.[6] This generally involves submitting an annual report that includes written policies and procedures.[7] Institutions must implement and submit to ORI written policies and procedures that comply with the revised regulation on or before **April 30, 2026**, unless the institution is approved to file a Small Institution Statement**.**

Institutions can submit their revised policies and procedures by visiting the ORI website and filling out the annual report online. For assistance with writing institutional policies and procedures, please contact ORI for guidance by calling (240) 453-8400 or emailing ORI-ComplianceReviews@hhs.gov.

[6] § 93.301(a)
[7] § 93.302(b-c)

Pertinent Provisions of 42 CFR Part 93 (2024)

§ 93.75 Application of effective date to research misconduct proceedings.

(a) An institution must follow this part for allegations received by the institution on or after January 1, 2026, except for the policies and procedures required under §§ 93.300(a) and 93.302(b), which must be implemented and submitted by due date of the annual report covering the 2025 reporting year, as specified by ORI.

(b) For allegations received by an institution before January 1, 2026, unless the institution and the respondent both elect in writing to follow this part, an institution must follow this part as published in the 2005 edition of the Code of Federal Regulations.

§ 93.300 General responsibilities for compliance.

Institutions must:

(a) Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part[.]

§ 93.302 Maintaining active research integrity assurances.

(b) Annual report. An institution must file an annual report with ORI, which contains information specified by ORI, on the institution's compliance with this part. The Institutional Certifying Official is responsible for certifying the content of this report and for ensuring the report is submitted as required.