

**Agency Guidance Snapshot: Public Health Service Policies on Research Misconduct: Notice of Proposed Rulemaking (NPRM)**

*The Yale Human Research Protection Program (HRPP) has launched the “Agency Guidance Snapshot” series. The purpose of the Agency Guidance Snapshots is to highlight recent agency guidance from the Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), and other federal agencies that specifically impacts Yale University and affiliate stakeholders who conduct or oversee **human subjects research**.*

**Please Note:** Yale University does not expect any immediate changes to policies due to this guidance; however, this guidance will be taken into consideration as policies and procedures are reviewed and revised in the future. Yale University may have additional requirements related to the topics covered in this guidance. For more information, please refer to the following Yale University Human Research Protection Program (HRPP) documents located on the HRPP website ([Policies, Procedures, Guidance, and Related Documents](#)) and in the Yale HRPP IRES-IRB Library ([IRES IRB LOGIN](#)): **1) Yale HRPP Policy and Standard Operating Procedure Manual**; **2) Yale HRPP Investigator Manual**; **3) Yale IRB Members and Chairs Manual**; and **4) HRPP Supplemental Guidance Manual**. Please also refer to [University Policies & Procedures](#) and policies published by the various Yale University schools and departments.

<b>Title of Document:</b>	Public Health Service Policies on Research Misconduct: Notice of Proposed Rulemaking (NPRM)
<b>Federal Agency:</b>	HHS: Office of Research Integrity (ORI)
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<b>Stakeholders Impacted:</b>	Investigators <input checked="" type="checkbox"/> Sponsor-Investigators <input checked="" type="checkbox"/> IRB/HRPP Staff, Chairs, & Members <input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/> (Institutional Leaders)
<b>Hyperlink to Document:</b>	<a href="https://www.federalregister.gov/documents/2023/10/06/2023-21746/public-health-service-policies-on-research-misconduct">https://www.federalregister.gov/documents/2023/10/06/2023-21746/public-health-service-policies-on-research-misconduct</a>

**Overview of Guidance Document:**

In this Notice of Proposed Rulemaking (NPRM), the Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI) proposes to revise the Public Health Service (PHS) Policies on Research Misconduct. The proposed revisions are based on the experience ORI and institutions have gained with the regulation since it was released in 2005. ORI anticipates release of the final rule in the summer of 2024, with implementation to begin a minimum of 4 months afterward. ORI will aim for an effective date of January 1, 2025, to simplify institutional reporting. Once this NPRM is finalized, ORI recognizes that some institutions may wish to implement the revised regulation for research misconduct proceedings already underway. As was done with the 2005 Final Rule, ORI intends that for any allegation of research misconduct received by HHS or an institution before the effective date of the revised regulation, regardless of the stage of the research misconduct proceeding, the proceeding will fall under the 2005 Final Rule.

**For any questions, please contact HRPP Assistant Directors  
Gina Larsen ([gina.larsen@yale.edu](mailto:gina.larsen@yale.edu)) or Cathi Montano ([cathleen.montano@yale.edu](mailto:cathleen.montano@yale.edu))**

Proposed changes to subparts A through E of the regulation ([42 CFR part 93](#); [70 FR 28370](#)) are outlined below and draw attention to areas that represent new approaches. Subpart A describes the purpose and fundamental precepts of the regulation. Subpart B provides definitions. Subpart C lists institutional responsibilities, and subpart D describes responsibilities of HHS and ORI. Finally, subpart E covers the process for respondents who wish to contest the ORI findings of research misconduct and HHS administrative actions.

## **Key Points for Institutional Leaders & the Research Community:**

### **Summary of Proposed Updates to Subpart A (Overview of Regulation)**

- **Confidentiality:** Adds clarifying language about the term “**confidentiality**”, explaining when and how disclosure may be made to “those who need to know.”
- **Anonymity:** ORI recognizes that **anonymity** is a concern for some complainants or witnesses in a research misconduct proceeding. Anonymity may be covered by institutional, state, or other policies, so no language on protecting anonymity is proposed in this NPRM. Instead, ORI proposes to issue guidance on protecting anonymity in materials collected throughout a research misconduct proceeding.
  - ORI welcomed public comment through December 2023 on maintaining anonymity for complainants or witnesses who request it, including whether to include provisions for such anonymity in the final rule.
- **Subsequent Use Exception:** Clarification regarding the “**subsequent use**” exception: NPRM retains the current six-year time limitation on applicability of the Final Rule but revises the “subsequent use” exception at §93.105(b)(1) to include additional information.
  - ORI welcomed public comment through December 2023 on how to further clarify the expectations and/or requirements related to the “subsequent use” exception.

### **Summary of Proposed Updates to Subpart B (Definitions)**

ORI is proposing revisions to definitions in subpart B and introducing new definitions, some of which align with other changes proposed throughout the regulation. ORI welcomed public comment on the proposed definitions through December 2023. Proposed changes include:

- Re-locating a few definitions without change, including: “**research misconduct**”, “**fabrication**”, and “**falsification**.”
- Revises definition of “**plagiarism**” to include more detail to differentiate what does and does not meet the definition. The term is also relocated to Subpart B.
- Adds definitions for some commonly-used terms to ensure clarity in usage, including: “**appeal**”, “**assessment**”, “**difference of opinion**”, “**institutional certifying official**”, “**institutional deciding official**”, “**research integrity**”, “**research integrity officer**”; and “**small institution**.”
- Adds new terms and definitions, including:
  - **Institutional Record** (definition found in the NPRM [HERE](#))
  - **Administrative Record** (definition found in the NPRM [HERE](#))
  - **Honest Error** (definition found in the NPRM [HERE](#))
  - **Intentionally, Knowingly and Recklessly** (definition found in the NPRM [HERE](#))
  - **Accepted Practices of the Relevant Research Community** (definition found in the NPRM [HERE](#))
  - **This Part** (definition found in the NPRM [HERE](#))

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### **Summary of Proposed Updates to Subpart C (Institutional Responsibilities)**

- Provides information and guidance about compliance and research integrity assurances, including specific guidance for small institutions.
- **Conflict of Interest:** Clarifies that institutions are not required to provide respondent with an opportunity to object to inquiry or investigation committee members; adds proposed language to clarify how an institution may provide respondents or complainants the opportunity to object to those chosen to conduct/support/participate in the research misconduct proceedings. If an institution chooses to provide one respondent (or one complainant) the opportunity to object, it must provide all respondents (or all complainants) in that proceeding the opportunity to object.
- **Sequestration of research records and other evidence:** Institutions must obtain and sequester all research records needed to conduct the research misconduct proceeding; when it's not possible to obtain the original research records or other evidence, an institution may obtain substantially equivalent copies.
- **Institutional Assessment:** New language outlines what's required; the criteria needed for an assessment to proceed to an inquiry; reporting requirements, and timeline for completion of assessments.
- **Institutional Inquiry:** Clarifications on the process, and proposed revision to allow institutional discretion in convening committees of experts to conduct reviews at the inquiry stage. Additional options are provided regarding who may do the inquiry review, noting that the institution may use one or more subject matter experts to assist them.
- Proposed clarity regarding proceeding to an investigation, which requires there be a reasonable basis for concluding that an allegation falls within the definition of research misconduct.
- Clarifies institutions are required to keep sufficiently detailed documentation of each inquiry to permit later assessment by ORI regarding reasons why the institution decided not to conduct an investigation.
- **Inquiry results and inquiry report:** inquiries are considered preliminary and “honest error” or “difference of opinion” determinations should not be made at the inquiry phase to support the dismissal of an allegation.
- **Institutional Investigation:** At the investigation stage, the institution may choose to add to or expand the ongoing investigation by including any new allegations pertaining to the same respondent or research records in question, rather than opening an inquiry for new allegations.
- **Institutional Record:** Institutions will be required to develop maintain, and provide an institutional record, to form the basis of any decisions by ORI, the Departmental Appeals Board Administrative Law Judge (“ALJ”), or HHS Suspension and Debarment Official. Additional guidance may be forthcoming on how to organize and submit the institutional record.

### **Summary of Proposed Updates to Subpart D (HHS and ORI Responsibilities)**

- Clarifies that the lack of an ORI finding of research misconduct does not overturn an institution's determination that the conduct constituted professional or research misconduct warranting remediation under the institution's policy.
- Clarifies actions ORI may take for institutional noncompliance.
- Indicates when and how ORI may disclose information about a research misconduct proceeding, including permitting ORI to publish notice of institutional research misconduct findings and implemented institutional actions. This notice would inform the public and research community that allegations of research misconduct have been addressed under the regulation and help to

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protect the health and safety of the public, promote the integrity of PHS supported research and the research process, or conserve public funds.

- ORI welcomed public comment on this proposed change through December 2023, particularly on the opportunity for a respondent to provide comment or information prior to the posting of such a notice.

### **Summary of Proposed Updates to Subpart E (Process for Respondents)**

- Outlines major revisions to the appeals process found at 42 CFR part 93, Subpart E which will provide a streamlined process for contesting ORI findings of research misconduct and HHS administrative actions.
  - The proposed appeals process would entail ALJ review of the administrative record, which includes all information provided by the respondent to ORI, to determine whether ORI's findings and HHS's proposed administrative actions other than suspension or debarment are reasonable and not based on a material error of law or fact.
  - The proposed appeals process also provides for the possibility of a limited hearing if the ALJ determines that there is a genuine dispute over material fact.
  - There would be no further opportunity to appeal ORI's findings and HHS's proposed administrative actions (other than suspension or debarment) within HHS.
- ORI welcomed comment through December 2023 on the scope of and need, or lack of need, for the limited hearing in proposed §93.511, as well as comment on the other proposed revisions to subpart E.

**For more related information, please see the following links to additional resources:**

- [HHS – The Office of Research Integrity](#)
- [HHS Releases Notice of Proposed Rulemaking to Update 2005 Public Health Service Policies on Research Misconduct](#)
- [A Message from the ORI Director on Proposed Revisions to the 2005 Public Health Service Policies on Research Misconduct \(42 CFR Part 93\)](#)
- [CITI Program - HHS Proposes Revisions to Research Misconduct Policies: A Call for Public Input](#)
- [Ropes & Gray - Health Care Attorneys Author Comment Letter on Proposed Changes to Federal Regulations on Research Misconduct](#)

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