hrp CONSULTING GROUP
Research Ethics and Compliance Management Solutions
Tel: 347.862.9321
Fax: 347.862.9323
www.thehrpconsultinggroup.com

Office of Research Integrity – Proposed Revisions to 2005 Final Rule on Public Health Service Policies on Research Misconduct

Fast Facts

- On October 6, 2023, the Office of Research Integrity published a Notice of Proposed Rulemaking (NPRM) to revise the 2005 Final Rule "Public Health Service Policies on Research Misconduct" (Federal Register :: Public Inspection: Public Health Service Policies on Research Misconduct)
- **Background:** The NPRM contains proposed revisions to the existing (2005) rule and includes "updates to clarify complex processes, vague concepts, and undefine terms in the existing regulation." The NPRM includes proposed revisions to definitions, processes, and major revisions to the appeal process.
- **Comment period** is on or before December 5, 2023. Comments may be submitted on any aspect of the NPRM; however, ORI is expressly requesting comments on items noted below.
- **Proposed timeframe**: ORI anticipates release of final rule in summer of 2024, with implementation to begin a minimum of 4 months afterward. The NPRM states ORI will aim for an effective date of January 1, 2025.
- **Applicability:** ORI intends that any allegations of research misconduct received by HHS or an institution before the effective date of the revised regulations will fall under the 2005 Final Rule.
    - ***ORI seeks comment*** *on aspects to consider if it were to entertain individual requests to apply the revised regulation to a particular ongoing proceeding.*

Summary of Proposed Revisions to Subpart A - General:

- Confidentiality: Adds clarifying language about confidentiality, and when/how/to whom disclosures may be made to "those who need to know."
- Anonymity: Since anonymity is a concern for some complainants/witnesses in a research misconduct proceeding, but may be covered by institutional, state, or other policies, no language on protecting anonymity is proposed in the NPRM. Instead, ORI proposes to issue guidance on protecting anonymity in materials collected throughout a research misconduct proceeding.
    - ***ORI specifically seeks comment*** *on maintaining anonymity for complainants or witnesses who request it, including whether to include provisions for such anonymity in the final rule.*
- Clarification regarding "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 specifically seeks comment*** *on how to further clarify the expectations and/or requirements related to the "subsequent use" exception.*

Summary of Revisions to Subpart B - Definitions:

- Re-locates some definitions without change: “research misconduct”, “fabrication”, and “falsification.”
- Revises definition of “plagiarism” to include more detail to differentiate what does and does not meet the definition.
- Adds definitions for some commonly-used terms: “appeal”, “assessment”, “difference of opinion”, “institutional certifying official,” “institutional deciding official”, “research integrity”, “research integrity officer”; and “small institution.”
- Adds new terms/definitions: “Institutional record”, “administrative record”, “honest error”, “intentionally, knowingly and recklessly”, “accepted practices of the relevant research community; “this part.”
    - ***ORI specifically seeks comment*** *regarding definitions for “research misconduct”, “fabrication”, “falsification”, “plagiarism,” or any other definitions.*

Summary of Revisions to Subpart C – Responsibilities of Institutions

- Provides information and guidance about compliance and research integrity assurances, including 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.
- 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.
- Proceeding to an investigation 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 of 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 Revisions to Subpart D

- Clarifies that the lack of an ORI finding of research misconduct does not overturn an institution's determination regarding professional or research misconduct under the institution's policy.
- Clarifies actions ORI may take for institutional noncompliance.
- Clarifies when and how ORI may disclose information about a research misconduct proceeding: ORI will be allowed to publish notice of institutional research misconduct findings and implemented institutional actions.
    - ***ORI specifically seeks comment*** *on when and how ORI may disclose information about a research misconduct proceeding, including a revision to permit ORI to publish notice of institutional research misconduct findings and implemented institutional actions, including comment on the opportunity for a respondent to provide comment or information prior to the posting of such a notice.*

Revisions to Subpart E

- Outlines "major" revisions to appeals process: Replaces current "de novo" review process by the appeals board with ALJ review of the administrative record, with the possibility of a limited hearing if the ALJ determines there is a genuine dispute over material fact. No further opportunity to appeal ORI's findings and HHS's proposed administrative actions (other than suspension or debarment) within HHS.
    - ***ORI specifically seeks comment*** *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.*