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ORI 2024 Final Rule - Public Health Service Policies on Research Misconduct (42 CFR Part 93)

Fast Facts

- On September 17, 2024, the Office of Research Integrity (ORI) published a Final Rule revising 42 CFR 93 Public Health Service Policies on Research Misconduct. The new regulation is displayed here: https://www.federalregister.gov/public-inspection/2024-20814/public-health-service-policies-on-research-misconduct.
- **Background:** ORI previously issued a Notice of Proposed Rulemaking (NPRM) suggesting changes to 42 CFR Part 93 based on the experiences of both ORI and institutions in applying the regulation since its implementation in 2005.

> "Since 2005, ORI and regulated entities experienced policy developments and technological changes applicable to research misconduct, such as the 2008 NIH Public Access policy; the 2023 NIH Data Management and Sharing policy; the shift to saving data on the cloud; and the ability to use artificial intelligence to detect image falsification, among many other developments. Therefore, ORI decided to revise part 93." [1]

- The Final Rule was developed to address the needs of the changing research landscape and was drafted in response to public feedback from ORI's NPRM and an internal review. It includes both significant and minor revisions, some of which are briefly described in the Highlights section below.
- **Applicability Date**: The new regulatory requirements are applicable beginning **January 1, 2026.**
- **Plans for ORI Guidance**: ORI plans on issuing further guidance along with sample policies and procedures, checklists, self-assessments, and flow charts to assist institutions in preparing for the Final Rule.
- **ORI Recommended Next Steps**:
  - Read and become familiar with the new regulation.
  - Review and update policies and procedures for handling research misconduct for PHS-funded work to align with the new regulation.
  - Start following the new regulation on **January 1, 2026.**
  - Submit new policies and procedures to ORI on or before **April 30, 2026**, with the 2025 Annual Report.

Final Rule Highlights

Subpart A - General

- The Subsequent Use Exception now only applies "when the respondent uses, republishes, or cites *to the portion(s) of the research record* that is alleged to have been fabricated, falsified, or plagiarized…"[§ 93.104(1)(i)]
- Confidentiality requirements now clarify that *institutions decide who "needs to know"* the identities of respondents, complainants, and witnesses. This may include IRBs, journals, editors, publishers, co-authors, and collaborating institutions. Once the institution makes a final decision on research misconduct, the restrictions on disclosing identities are lifted. [§ 93.106]
- Evidentiary standards now require that for the absence of research records to be considered evidence of misconduct, the respondent must have intentionally destroyed them *or claimed to possess the records but refused to provide them*. [§ 93.105(b)]

Subpart B - Definitions

- Added or revised definitions of commonly used terms, including but not limited to:

Accepted practices of the relevant research community § 93.200	Administrative record § 93.202	Institutional record § 93.220	Intentionally § 93.221	Knowingly § 93.223	Recklessly § 93.231	Research Integrity Officer § 93.233

- "Plagiarism" now includes verbatim copying that misleads but excludes self-plagiarism and authorship disputes. [§ 93.227]

Subpart C – Responsibilities of Institutions

- Sequestered records may now also include *copies* of records that are substantially equivalent and needed to conduct the research misconduct proceeding, if originals aren't available. Additional relevant items may also be sequestered *after* the initial sequestration. [§ 93.305]
- Clarifies that institutions can include additional respondents during investigation without needing to conduct *separate inquiries* for each. [§ 93.305(d); § 93.310(c)(2)]
- Adds than when *multiple institutions* are involved, one should act as the *lead institution* to collect research records from other institutions. [§ 93.305(e)]
- Clarifies that inquiries may be conducted by *an individual* (e.g., Research Integrity Officer) instead of a committee. [§ 93.307(e)(2)]
- Inquiry Reports must include more detailed information such as interview transcripts, timeline and procedural history, an inventory of sequestered research records, and any institutional actions. [§ 93.309(a)]
- Institutional investigation interview transcript requirements now also include *sharing all transcripts with the respondent* (including transcripts of witness interviews). [§ 93.310(g)]
    - Regarding the redaction of transcripts, ORI notes the following in IV. Significant Comments Not Resulting in Changes, BB: "Some commenters suggested revising NPRM section § 93.305(g)(5) to require institutions to redact all interview transcripts before

forwarding them to the respondent, to protect interviewees' identities. ORI left this section unchanged and moved it to § 93.310(g) because policies regarding interview transcriptions prior to the investigation phase should be left to the discretion of institutions."

- The investigation timeframe is extended from 120 to 180 days. [§ 93.311]
- Investigation Reports now require additional documentation like an inventory of sequestered materials, description of sequestration conduct, transcripts of all interviews, and any scientific or forensic analysis. [§ 93.313]
- Transmittal of the entire *institutional record* (as defined at § 93.220) to ORI is now required after the institution makes a final determination. [§ 93.316]

Subpart D – Responsibilities of the U.S. Department of Health and Human Services

- Clarifies that an institution's determination of professional or research misconduct is made *independently* of ORI's findings. [§ 93.404]

Questions

Contact ORI with questions at AskORI@HHS.gov.

References

- Final Rule. https://www.federalregister.gov/public-inspection/2024-20814/public-health-service-policies-on-research-misconduct
- Ropes and Gray: "ORI Issues Final Changes to Research Misconduct Regulations: Key Reforms and Lingering Complexities". https://www.ropesgray.com/en/insights/alerts/2024/09/ori-issues-final-changes-to-research-misconduct-regulations-key-reforms-and-lingering-complexities
- Office of Research Integrity (ORI) Blog: "ORI is Updating its Policies on Research Integrity to Meet the Demands of the Modern Research Environment". https://ori.hhs.gov/blog/ori-updating-its-policies-research-integrity-meet-demands-modern-research-environment
- Office of Research Integrity (ORI) – Final Rule Stakeholder Webinar. https://ori.hhs.gov/blog/join-ori-webinar-2024-final-rule-friday-september-20-2024 (slides not posted as of 9/23/24).