ORI Issues Final Changes to Research Misconduct Regulations: Key Reforms and Lingering Complexities

Mark Barnes, Barbara Bierer, Minal Caron, and Madhu Purewal

ROPES & GRAY

September 19, 2024

Reminders

- A copy of the slides and a recording of today's program will be circulated to all attendees.
- You will have an opportunity to ask questions during the presentation. – Please submit questions via the Q&A function.
- This presentation is meant to assist in understanding possible interpretations and approaches to compliance and does not constitute legal advice from Ropes & Gray.
  - Each institution should consult its own legal counsel on these issues.
- If you are interested in receiving CLE credit, please fill out the Attorney Affirmation form that was circulated with the confirmation e-mail for today's program.
  - At the end of the presentation, we will give you the code to add to the form so you can receive CLE credit.
  - Please send completed forms to CLE.Team@ropesgray.com.

AGENDA

- Background
- Key Changes in the Final Rule
- Changes That Can Be Implemented Prior to the Effective Date
- Discussion: Question and Answer Period

AGENDA

- **Background**
- Key Changes in the Final Rule
- Changes That Can Be Implemented Prior to the Effective Date
- Discussion: Question and Answer Period

Background: Part 93 Research Misconduct

- Current research misconduct regulations at 42 C.F.R. Part 93 (“Part 93”) were promulgated **May 17, 2005**, at 70 Fed. Reg. 28370–28400.
- ORI proposed revisions **October 6, 2023**, at 88 Fed. Reg. 69583–69604 (“NPRM”).
- ORI sought public comments and received 199, 126 of which were from research institutions or related entities such as associations, advocacy groups, and industry.
- HHS released a final rule **September 12, 2024**, which was formally published in the Federal Register on **September 17, 2024** at 89 Fed. Reg. 76280–76309 (“Final Rule”).
- Compliance with this rule is required effective **January 1, 2026**, and institutions are required to submit revised policies and procedures to ORI in annual reports beginning **April 30, 2026**.

Background: Research Misconduct Proceedings: Current Regulations

- Currently, the regulations set forth a three-part investigational process:
  - **Threshold review of allegation:** Is the allegation "sufficiently credible and specific so that potential evidence of research misconduct may be identified"? *42 CFR § 93.307(a)(3).*
  - **Inquiry:** Asks fact-finder to determine whether preliminary fact-finding "indicates that the allegation may have substance" and to prepare an inquiry report. *42 CFR § 93.307(d).*
  - **Investigation:** Full review of evidence and development of investigation report. *42 CFR § 93.310.*
    - "Evidence" means "any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact." *42 CFR § 93.208.*

Background: OSTP Research Misconduct Policy

- White House Office of Science and Technology Policy ("OSTP") Federal Research Misconduct Policy, issued on December 6, 2000 (the "**2000 OSTP Policy**").

> "Applies to federally funded research and proposals submitted to Federal agencies for research funding" and required that all "Federal agencies that conduct or support research . . . implement this policy."

> Defines "research misconduct" as "**fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results**," which represent a "**significant departure from accepted practices**"; have been "**committed intentionally, or knowingly, or recklessly**"; and be "**proven by a preponderance of evidence**."

> Sets forth **three phases to reviewing allegations**: "(1) an **inquiry**—the assessment of whether the allegation has substance and if an investigation is warranted; (2) an **investigation**—the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies; (3) **adjudication**—during which recommendations are reviewed and appropriate corrective actions determined."

- **ORI regulations must be consistent with this policy**; a primary purpose of the ORI Part 93 regulations issued in 2005 was to bring the ORI regulations into compliance with the 2000 OTSP Policy.
  - ORI's changes to Part 93 cannot vary from the structure/definitions outlined under the OSTP Policy.

Background: Material Changes from NPRM to Final Rule

#	Section	Proposed Rule (October 6, 2023)	Final Rule (September 12, 2024)
1	**§ 93.102 Applicability**	Funding recipients are responsible for the compliance of their subrecipients with Part 93.	Removed after significant criticism in comments.
2	***§ 93.104 Time Limitations***	ORI, not institutions, makes the final determination of whether the subsequent use exception to the six-year statute of limitations applies.	After significant criticism, revised to require institutions to document their determination but not to include any mechanism whereby ORI would review and approve the institutional determination.
3	**§ 93.106 Confidentiality**	Institutions must inform respondents, complainants, and witnesses prior to interview if and how their identity may be disclosed.	Removed after significant criticism. Limitation on disclosure of identities no longer applies after an institution has made a final determination.
4	**§ 93.305 General Conduct of Research Misconduct Proceedings**	Institutions must consider all additional possible responsible parties including principal investigator, collaborators, and lab members as potential respondents.	Removed after significant criticism in comments.
5	***§ 93.305 General Conduct***	All interviews must be transcribed.	Revised to a requirement that all interviews in investigation stage must be transcribed and all transcribed interviews at any stage must be shared with respondent.
6	**§ 93.306 Institutional Assessment**	New formalized assessment stage included a requirement to produce an assessment report with extensive mandatory content.	Revised after significant criticism in comments, to a more flexible requirement to “[d]ocument the assessment.”

Background: Material Changes from NPRM to Final Rule

#	Section	Proposed Rule (October 6, 2023)	Final Rule (September 12, 2024)
7	***§ 93.307 Institutional Inquiry***	Assessment stage automatically proceeds to inquiry if assessment is not completed within 30 days.	Removed after significant criticism in comments.
8	**§ 93.307 Institutional Inquiry**	A determination of honest error or difference of opinion must not be made at the inquiry stage; it must be made in the investigation stage, if at all.	Removed after significant criticism in comments.
9	**§ 93.307 Institutional Inquiry**	Institutions must request an extension from ORI if the inquiry exceeds 60 days.	Removed after significant criticism in comments.
10	**§ 93.313 Investigation Report**	Voting or split decisions by the investigation committee members are not permitted in the final recommendation in the investigation report.	Removed after significant criticism in comments.
11	**§ 93.410 Final HHS Action with No Settlement or Finding of Research Misconduct**	HHS may publish institutional research misconduct findings and institutional actions even when an HHS action does not result in a settlement or finding of research misconduct.	Removed after significant criticism in comments.

AGENDA

- Background
- **Key Changes in the Final Rule**
- Changes That Can Be Implemented prior to the Effective Date
- Discussion: Question and Answer Period

Key Changes in Final Rule

1. Clarification and Changes to Assessment and Inquiry Procedures
2. Content of Reports and Institutional Record
3. Investigation Timeframe
4. Definitions for Intent
5. Plagiarism
6. Subsequent Use Exception
7. Confidentiality
8. Respondent's Retention of Research Records
9. Interview Transcripts
10. Sequestration
11. Finality of Institutional Decisions
12. Multiple Respondents
13. Multiple Institutions

1. Clarification and Changes to Assessment and Inquiry Procedures

Assessment:

- The Final Rule formalizes the pre-inquiry assessment.
- The **RIO or another designated institutional official** is required to evaluate, determine and document whether the allegation (i) falls within the definition of research misconduct under Part 93; (ii) is within the jurisdiction of Part 93; and (iii) is sufficiently credible and specific such that potential evidence of research **misconduct may be identified.**

Inquiry:

- Typically, institutions appoint a committee to conduct the inquiry and investigation stages.
- The Final Rule clarifies that the **RIO or another designated institutional official may conduct the inquiry**.

2. Content of Reports and Institutional Record

Inquiry Report

- Under the current rule, institutions must provide ORI, after a finding that an investigation is warranted, an inquiry report including but not limited to a description of the allegations, the relevant PHS support, the basis for proceeding to investigation, and any comments on the report by the respondent.
- The Final Rule **expands the required components of the inquiry report.** New requirements for inquiry reports include:
  - The composition of the inquiry committee (if a committee is used)
  - **Inventory of sequestered research records and evidence and description of how sequestration was conducted**
  - **Transcripts of any transcribed interviews**
  - Timeline and procedural history
  - Any scientific or forensic analyses conducted
  - Basis on which any allegations do not merit investigation
  - **Any institutional actions implemented, including communications with journals or funding agencies**

2. Content of Reports and Institutional Record

Investigation Report

- Under the current rule, institutions must provide ORI, after an investigation has concluded, an investigation report, which includes a description of the allegations, list of relevant PHS support, policies and procedures followed, relevant records and evidence, a statement of findings, and any comments made by the respondent.
- The Final Rule **expands the required components of the investigation report.** New requirements for investigation reports include:
  - Composition of the investigation committee
  - **Inventory of sequestered research records and evidence, except records not relied upon, and description of how sequestration was conducted**
  - **Transcripts of all interviews conducted**
  - Identification of publications, manuscripts, PHS funding applications, progress reports, presentations, research records, etc., containing material linked to the alleged research misconduct
  - Any scientific or forensic analyses conducted

2. Content of Reports and Institutional Record

Institutional Record

- Under the current rule, institutions must provide ORI, after an investigation has concluded, an investigation report, statement of final institutional action, statement of findings, and statement of administrative actions.
- Under the Final Rule, institutions must now **transmit a full institutional record to ORI after a final determination in research misconduct proceedings.** New requirements for transmission to ORI include:
  - All records compiled or generated and relied upon in the proceedings
  - Documentation of the assessment stage
  - Inquiry report (if inquiry stage was reached)
  - Transcripts of all transcribed interviews
  - Record of any institutional appeal
  - Index listing all research records and evidence that the institution compiled during the proceeding
  - General description of records that were sequestered but not considered or relied on

3. Investigation Timeframe

- Institutions have historically opined that the 120-day requirement for investigations under the current rule is too short.
- The Final Rule **extends the investigation time limit from 120 days to 180 days.**
- Institutions must still request an extension from ORI if the investigation exceeds 180 days, and institutions must document the reasons for exceeding the deadline.
  - Preamble commentary accompanying the Final Rule reiterates that ORI will expect substantive updates in the extension request that justify the need for an extension

> "ORI will continue to work closely with institutions that *request and substantiate* the need for an extension"

4. Definitions for Intent

- A finding of intent is required for a finding of research misconduct, and a finding of intent or lack of intent must be explained in an institution's investigation report.
- The Final Rule adds definitions for the forms of intent necessary for a finding of research misconduct. *42 CFR § 93.104.*
  - "**Intentionally**" means "to act with the aim of carrying out the act."
  - "**Knowingly**" means "to act with awareness of the act."
  - "**Recklessly**" means "to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism."

5. Plagiarism

- Plagiarism is a form of research misconduct.
- "Plagiarism" means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.
- The Final Rule clarifies the definition of plagiarism, including codifying longstanding ORI guidance that self-plagiarism and authorship disputes do not constitute plagiarism (and therefore do not constitute research misconduct):
  - Plagiarism includes the **unattributed verbatim or nearly verbatim** copying of sentences and paragraphs **from another's work** that **materially misleads** the reader regarding the contributions of the author. **It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology.**
  - Plagiarism does not include **self-plagiarism** or **authorship or credit disputes**. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

6. Subsequent Use Exception

- Part 93 "applies only to research misconduct occurring within **six years** of the date HHS or an institution receives an allegation of research misconduct," with certain exceptions.
- The "**subsequent use exception**" states, "The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication **or other use for the potential benefit** of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized." 42 CFR § 93.105(a).
- The Final Rule narrows the subsequent use exception, such that the exception only applies "when the respondent uses, republishes or cited **to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized**, . . . within six years of when the allegations were received."
- In practice, it may be difficult in many cases for institutions to determine when a "portion" of a research record has been cited because citations in a scientific publication do not typically reference a particular figure or portion of the cited publication.
  - While the subsequent use exception has been narrowed, it may require significant additional diligence on the part of RIOs and institutions to evaluate the applicability of the subsequent use exception to the research records under scrutiny.

7. Confidentiality

- Under the current regulations, respondent and complainant identities may be disclosed only on a need-to-know basis, "**to the extent possible**," and as allowed by law. 42 CFR § 93.108(a).
- The Final Rule stipulates that **the confidentiality restriction only applies until the institution has made its final determination in the research misconduct process**.
- The Final Rule clarifies the concept of "need to know." Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions.

8. Respondent Record Retention

- Part 93 currently states that a respondent's **failure to provide research records** adequately documenting the questioned research **is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent destroyed the records, failed to maintain them, or failed to produce them in a timely manner**. 42 C.F.R. § 93.105(b).
- The Final Rule permits such an evidentiary finding only if the respondent claims to possess the records but **refuses to provide them upon request.**
- Under the Final Rule, failure to provide research records can still be considered by an institution as part of the overall evaluation of evidence in the case. However, respondents and their attorneys are likely to argue that the revised language should be deemed to foreclose, or at least call into question, an institution's ability to draw negative inferences from the failure to maintain relevant records.

9. Interview Transcripts

- Under the Final Rule, interviews in the investigation stage **must be transcribed** and the respondent must have access to interview transcripts. **Materials shown to interviewees must also be numbered as exhibits**, referred to by exhibit number during the interview, and included in the institutional record along with the exhibits.
- Interviews conducted at any stage of the proceeding, if transcribed, must be **shared with the respondent**.
  - Mandate for transcripts to be shared with respondent weighs in favor of transparency and due process for the respondent.
  - However, this requirement could have chilling effect on willingness of witnesses to provide candid testimony (or to provide testimony at all).
  - Institutions that do not routinely provide transcripts of all interviews to the respondents will need to develop a standard approach for informing each witness as to how their transcripts will be used in the research misconduct proceeding.
  - Question remains as to whether transcripts could be redacted to shield identities of witnesses and thus mitigate risks of retaliatory behavior and related concerns.

10. Sequestration

- The current regulations require institutions to sequester "**all the research records and evidence** needed to conduct the research misconduct proceeding" beginning "on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier." *42 C.F.R. § 93.307(b).*
- The Final Rule clarifies that (1) when original research records cannot be obtained, copies of records that are "**substantially equivalent in evidentiary value**" will fulfill the sequestration requirement and (2) subsequent or interim sequestration should occur **whenever new records become known** (in addition to the initial sequestration prior to the respondent being notified of the allegations).
- As previously mentioned, the Final Rule now requires both inquiry and investigation reports to include an "inventory of sequestered research records" and a "description of how sequestration was conducted."
- **In conclusion, the Final Rule makes clear that ORI expects significant attention to detail regarding sequestration, from documentation of sequestration activities in inquiry/investigation reports, to preparation of an index of sequestered materials that extends beyond the key evidence relied upon by an inquiry or investigation committee and must be transmitted to ORI at the conclusion of the investigation.**

11. Finality of Institutional Decisions

- The current regulations contain no clear statement that an institution's determination of whether research misconduct occurred is independent of any finding from ORI regarding research misconduct.
- The Final Rule clarifies that **institutional determinations are final.**

> "*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.*"

12. Multiple Respondents

- The Final Rule adds a clarification that new inquiries are not necessary if **new respondents** are added to a proceeding.

> *"If an institution identifies additional respondents during an inquiry or investigation, the institution is not required to conduct a separate inquiry for each new respondent. However, each additional respondent must be provided notice of and an opportunity to respond to the allegations, consistent with this subpart."*

13. Multiple Institutions

- The Final Rule adds procedural guidelines for **multi-institutional proceedings**.

> *"When allegations involve research conducted at multiple institutions, one institution must be designated as the lead institution if a joint research misconduct proceeding is conducted. In a joint research misconduct proceeding, the lead institution should obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution."*

- Increasingly, institutions are documenting multi-institutional processes in a written document (e.g., Memorandum of Understanding or other formal agreement). The Final Rule does not require implementation of a written agreement for multi-institutional proceedings. However, the preamble to the Final Rule acknowledges that commentators sought additional guidance on how to handle multi-institutional proceedings and that ORI "intends to issue further guidance on this topic."

AGENDA

- Background
- Key Changes in the Final Rule
- Policies That Can Be Implemented Prior to the Effective Date
- Discussion: Question and Answer Period

Changes That Can Be Implemented prior to the Effective Date

- While HHS estimated 16 hours for an institute to implement the Final Rule, the majority of institutions surveyed by COGR estimated more than 40 hours to implement,[1] with some institutions estimating hundreds of hours.
- Implementation of Final Rule provisions that do not contravene the current regulations can also clarify and eliminate uncertainties or inconsistences in some policies and procedures, including with respect to:
  - Greater flexibility as to the fact-finding at the inquiry stage
  - Content of Inquiry and Investigation Reports
  - Definitions of Intent
  - Definition of Plagiarism
  - Multi-Institution Proceedings

1: Comment from COGR, HHS-OASH-2023-0014, HHS-OASH-2023-0014-0001, 2023-21746, December 12, 2023, https://www.regulations.gov/comment/HHS-OASH-2023-0014-0074.

Changes That Can Be Implemented prior to the Effective Date

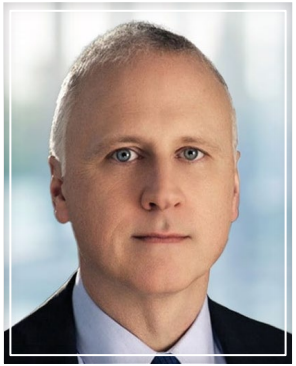
1. **Clarification and Changes to Assessment and Inquiry Procedures**
2. **Content of Reports and Institutional Record**
3. Investigation Timeframe
4. **Definitions for Intent**
5. **Plagiarism**
6. **Subsequent Use Exception**
7. **Confidentiality**
8. Respondent's Retention of Research Records
9. **Interview Transcripts**
10. **Sequestration**
11. **Finality of Institutional Decisions**
12. **Multiple Respondents**
13. **Multiple Institutions**

AGENDA

- Background
- Key Changes in the Final Rule
- Policies That Can Be Implemented Prior to the Effective Date
- **Discussion: Question and Answer Period**

QUESTIONS

Presenters



Mark Barnes
mark.barnes@ropesgray.com
617.951.7827

Barbara Bierer
bbierer@bwh.harvard.edu
617.732.8990

Minal Caron
minal.caron@ropesgray.com
617.235.4733

Madhu Purewal
mpurewal@mdanderson.org