US Department of Health and Human Services
Office of Research Integrity

Updates to the Public Health Service Policies on Research Misconduct

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OASH | Office of the Assistant Secretary for Health

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Disclosure

The opinions presented here are ours and do not reflect that of the Office of Research Integrity (ORI) and/or the Office of the Assistant Secretary of Health (OASH). We have no financial disclosures or incentives to declare. We have no actual or potential conflict of interest in relation to this program/presentation.

The Role of the U.S. Office of Research Integrity

The Office of Research Integrity (ORI) within the Department of Health and Human Services (HHS) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the HHS Secretary, with the exception of the regulatory research integrity activities of the Food and Drug Administration.

The 2024 Final Rule Overview

- The Public Health Service (PHS) Policies on Research Misconduct (42 CFR 93) published on September 17, 2024.
- This regulation replaces the previous 2005 rule.
- ORI updated the regulation to provide a transparent framework for today's dynamic research environment.
  - **The 2024 Final Rule balances the needs of the research community with ORI's oversight responsibilities.**

Timeline of the ORI Final Rule

- Request for Information (RFI) released on September 1, 2022.
- Notice of Proposed Rulemaking (NPRM) released on October 6, 2023.
  - ✓ The NPRM comment period extended by 30 days.
- **The public responded, and ORI listened.**
  - **Final Rule published on September 17, 2024.**

Major Highlights of the 2024 Final Rule

- Clarifies institutional confidentiality requirements
- Provides institutional discretion for determination of honest error and subsequent use
- Revises current definitions and adds new definitions
- Codifies phases of research misconduct proceedings
- Revises appeals process

Clarifies Institutional Confidentiality Requirements

- Clarifies the confidentiality period.
- Makes clear journals/editors/publishers may have need to know.
- Makes clear institutions can correct the research record.
- Specifies that institutional findings are separate from ORI findings.
- ORI does not publish institutional findings but reserves the right to publish findings from its own oversight review.

Specified Institutional Discretion for Findings of Honest Error and Subsequent Use

- Eliminates prohibition of consideration of honest error & difference of opinion before the investigation phase.
- Allows institutions to determine if the subsequent use exception is applicable.
  - **Requires documentation for later review by ORI if needed.**

Revised and New Definitions

- Defines *Intentionally, Knowingly,* and *Recklessly.*
- Adds *Institutional Record* with clear specifications on what must be included.
- Defines *Research Integrity Officer*.
- Adds *Institutional Deciding Official.*
- Adds *Institutional Certifying Official.*

Outlines the Lifecycle of Research Misconduct Proceedings

- Defines the institutional assessment.
- Lengthens the institutional inquiry from 60 to 90 days.
- Clarifies institutional discretion for convening committees and conducting interviews.
- Lengthens the institutional investigation from 120 to 180 days.
- Requires formal interview transcripts at investigation.
  - ✓ Clarifies that separate inquiries in cases of multiple respondents are up to institutional discretion.
- Outlines the process when multiple institutions are involved.

Streamlines Appeals Process

- Administrative Law Judge (ALJ) no longer completes a *de novo* review.
- The ALJ reviews the administrative record, produced by institutions and supplemented by ORI.

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Preparing for Implementation of the Final Rule

ORI Final Rule: Institutional Perspective

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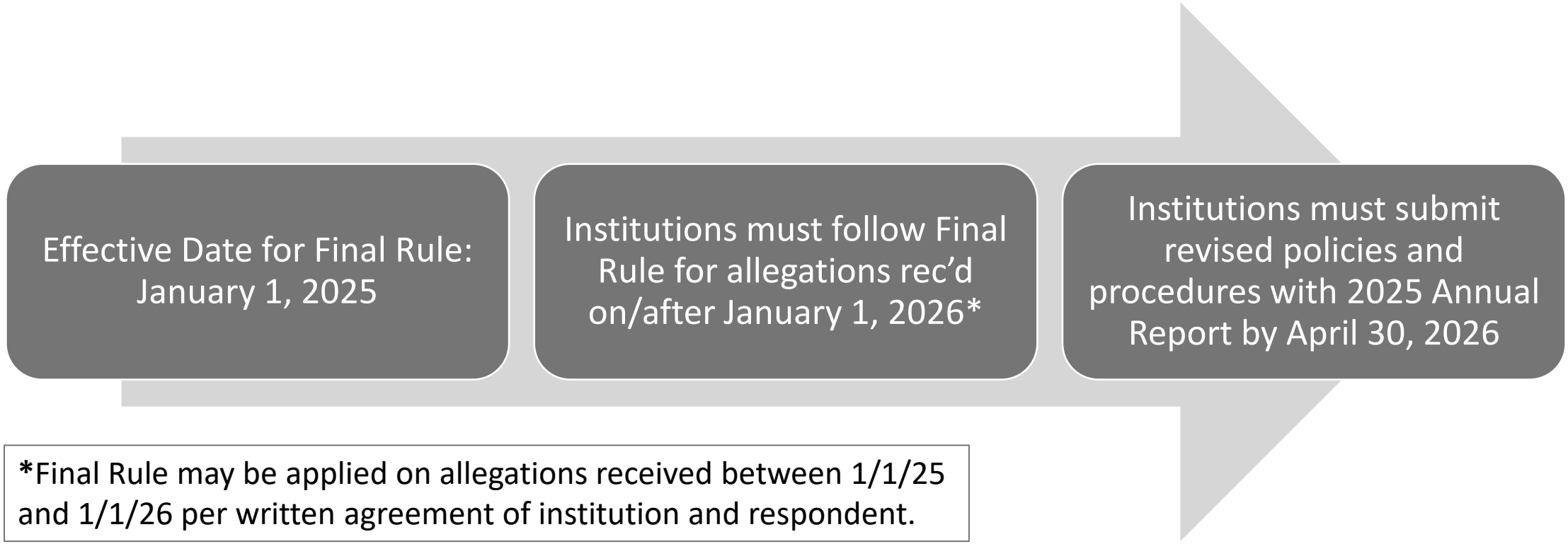
Compliance Timeline



*Final Rule may be applied on allegations received between 1/1/25 and 1/1/26 per written agreement of institution and respondent.

Timeline Considerations

- Cases that overlap 2025 – 2026
- Can/should you try to implement the 2026 Rule early?
- How will your institution handle the issues concerning application of 2026 rule to 2025 proceedings “per written agreement” of institution and respondent?
  - **Will you offer this as an option? “Must” you offer it as an option?**
- Need to assess current policy and procedures to identify significant changes
- Who has to approve new institutional policy? Backing into timeline for drafting new policy

Institutional Policies and Procedures & Training

- Updating of policies, processes, and training materials to reflect new and modified definitions.
  - **ORI anticipates publishing new template policies.**
  - **Institutions will need to determine if they will use plain language or mirror regs.**
  - **Multi-institutional proceedings must now be specifically addressed.**
- Institutions can consider how to apply flexibility in new rule.
- Research integrity staff and committees will need guidance in areas identified in the Final Rule especially those which result in changes in institutional policy and procedures.

General Conduct of the Review

- Sequestration requirements permits obtaining copies of data/other evidence “so long as those copies are substantially equivalent in evidentiary value.”
  - **Institutions will need to determine how sequestration will be implemented, including how it should be codified in policies.**
- Applying the 6-year Limitations Period
  - **Institutions will need to determine how subsequent use exceptions will be applied and documented.**
- Confidentiality
  - **Need-to-Know criteria are more specific and provide examples, like journals; institutions will need to translate to policies and procedures—and how will these policies be defended in the event of lawsuits.**

Phases of Review

- **Assessment:**
  - **Assessment is formalized; policy and procedures must include documentation of assessment.**
- **Inquiry**
  - **RIOs may explicitly conduct inquiries.**
  - **Institutions are not required to provide complainant with notice of whether an investigation is warranted or provide relevant provisions of inquiry report.**
  - **Inquiry report and institutional records specifications are more detailed**
  - **There is no requirement to conduct a separate inquiry for additional respondents identified during inquiry or investigation. Institutions will need process for notification of additional respondents and what due process is needed depending on when identified.**

Phases of Review

- **Investigation**
  - The same committee may investigate multiple respondents, but there must be separate investigation reports and determinations for each respondent.
  - Respondent must not be present for witness interviews but must receive interview transcript. Policies and procedures should reflect how an institution redacts transcripts.
  - Complainant may, but is not required to be provided with copy of draft investigation report.
  - More detailed requirements for investigation reports highlight the need for staff training.
  - Clarification of Institutional Deciding Official's responsibilities will be necessary.
- **Institutional Appeal**
  - There is no time limit for appeals processes but institutions must notify ORI of any institutional appeal, including appeals of institutional decisions and sanctions;
  - Complete "institutional record" must be transmitted to ORI at conclusion of appeal. Compiling and maintaining this records is critical.

Early Closing of a Proceeding/Admissions

- ORI must be consulted if a case is closed early at inquiry, investigation, or appeal because (a) respondent admits guilt or (b) a settlement has been reached AND there are standards for admission statements.
  - **Guidance will be needed for circumstances in which institutions consult with ORI in unique situations.**

Next Steps

Areas of Potential ORI Guidance

- Institutions use of committee, consortium, or person to conduct proceedings and allowing respondents/complainants to object to committee/consortium members
- Assessment reports
- Maintaining a “research integrity assurance” and types of policies/procedures institutions must make publicly available
- Definition of “Research Integrity”
- Definition of “Research Record”
- Recommended practices for “pursuing leads”
- Fostering an environment of research integrity and developing/evaluating training programs
- Handling cases that involve multiple institutions

Areas of Additional ORI Policymaking

- Application of the subsequent use exception
- Assessment phase
- Self-plagiarism

Questions and Comments?