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Tips for Implementing the Final Rule

Use this tip sheet to update your institutional policy based on the new U.S. Department of Health and Human Services ("HHS") Office of Research Integrity ("ORI") Final Rule requirements.

Compliance with the Final Rule is required by January 1, 2026

Update Definitions	• **Allegation**: Communication brought directly to the RIO.
	• **Intent Levels**
	  ◦ Intentionally– acting with the aim of carrying out the act.
	  ◦ Knowingly – acting with awareness of the act.
	  ◦ Recklessly – proposing, performing, or reviewing research with indifference to known risks of fabrication, falsification, or plagiarism.
	• **Plagiarism:** Differentiate it from self-plagiarism and authorship disputes.

Timelines	• **Inquiry:** Previously 60 days, now 90 days • **Investigation:** Previously 120 days, now 180 days ***Recommendation: Include provisions for extensions, ensuring updates and reasons for extensions are documented.**
Lack of Evidence	A finding of research misconduct can no longer be made solely upon a respondent's failure to provide relevant research records as the Final Rule now specifies this determination can be made only if the respondent claims to possess the records but *refuses to provide them upon request*
Subsequent Use Exception	Applies *only* to the respondent's use, republication, or citation to "the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized
Institutional Findings	Ensure it is clear that institutional decisions regarding misconduct are independent of ORI findings
Flexibility	• **Assessment:** The RIO or another designated official is able to review and document the assessment. Only involves the review of readily accessible information. • **Honest Error Determinations:** This determination is no longer limited to investigation • **Inquiry:** The Research Integrity Officer (RIO) or designated official can conduct inquiries • **Adding Respondents and Allegations:** Respondents and allegations can be added during ongoing investigations • **Confidentiality**: "Need to know" has been expanded and the restriction on sharing information only applies until the institution has made its final determination in the research misconduct process

Training and Awareness

- **Communicate changes with:**
  - Standing committees
  - Deciding Official
  - Research Integrity support staff
  - The research community

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Policy vs Standard Operating Procedures (SOP)

Some Final Rule changes may require new or updated Standard Operating Procedures. See potential SOPs:

- **Interviewing:** Prepare to transcribe all interviews and share the transcripts with the respondent.
- **Documentation Standards**: Set clear standards for documenting the entire research misconduct process, including assessment, inquiry and investigation, as well as how data was sequestered and an inventory of sequestered evidence that was used to make a determination.
- **Multi-institutional investigations:** Outline how your institution would handle investigations involving multiple institutions. Joint vs Parallel proceedings.
- **Adding Respondents and/or Allegations:** Describe procedures for adding Respondents and/or allegations during ongoing proceedings.

***Recommendation: Draft policy language to be 1) timeless, 2) flexible, and 3) applicable to all federal agencies and sponsor. Capture prescriptive processes in SOPs.**

Report Requirements

- **Inquiry Report Requirements:**
  - Identification of the respondent
  - Description of research misconduct allegations and PHS support
  - Basis for recommending an investigation
  - Comments from the respondent or complainant
  - Description of analyses conducted
  - Transcripts of any interviews that were transcribed
  - Timeline and procedural history
  - Inventory of sequestered research records
  - Any institutional actions implemented
- **Investigation Report Requirements:**
  - Same as those listed for Inquiry
  - Revised allegations if applicable
  - Additional data sequestration if applicable

Note: Final records should not be submitted to ORI until after any institutional appeals. If an appeal is filed after the institution has transmitted the institutional record, the institution must notify ORI so the agency can postpone oversight review until the institutional appeal is complete.

***Recommendation: Create a checklist of report requirements.**

New Roles

The Certifying Official is the institutional official responsible for:

- § assuring on behalf of an institution that the institution complies with the institution's policies and procedures for addressing allegations of research misconduct
- § certifying the content of the institution's annual report, which contains information specified by ORI and ensuring the report is submitted to ORI

The Suspension and Debarment Official (SDO) is the HHS official authorized to impose suspension and debarment, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the Federal Government.

These helpful tips should be verified and should not be used solely to determine how to be compliant with the new Final Rule. *Annual reports submitted to ORI April 30, 2026 and beyond must include submission of revised policies based on these changes.

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