

Comparison of Key Provisions in 42 C.F.R. Part 93

Topic	Current Rule ¹	Final Rule ²
1. Individuals Conducting the Inquiry	Most institutions appoint a committee to conduct the inquiry.	Clarification that an inquiry need not be conducted by a committee; a Research Integrity Officer or other designated official may conduct the inquiry.
2. Content of Inquiry Report	Inquiry report should include identification of the respondent, a description of the research misconduct allegations and PHS support, and a basis for recommending whether the allegations warrant an investigation (including comments on the inquiry report from the respondent or complainant).	Inquiry report should <u>also</u> include a description of analyses conducted, transcripts of any interviews that were transcribed, a timeline and procedural history, an inventory of sequestered research records, and any institutional actions implemented. Because institutions are required to share the inquiry report with respondents, respondents now are granted access to all transcripts of transcribed interviews.
3. Content of Investigation Report	Investigation report should include the allegations, a description of the PHS support, the institutional charge, the institution's policies and procedures, research records and evidence, a statement of the findings, and comments from the respondent or complainant.	Investigation report should <u>also</u> include an inventory of sequestered materials and how sequestration was conducted, transcripts of all interviews, and any scientific or forensic analyses conducted.
4. Investigation Timeframe	Investigation should be completed within 120 days (extensions are routinely granted).	Investigation should be completed within 180 days (language also added clarifying that extensions will be considered based on institution's providing specific updates and reasons for the need for an extension).
5. Definition of Recklessness	Stipulates that a finding of research misconduct requires that the misconduct be committed intentionally, knowingly, or recklessly but no definition for these terms.	<p>“<u>Intentionally</u>” is “to act with the aim of carrying out the act.”</p> <p>“<u>Knowingly</u>” is “to act with awareness of the act.”</p> <p>“<u>Recklessly</u>” is “to act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.”</p>

¹ 42 C.F.R. Part 93.

² The Final Rule is to be published in the Federal Register on September 17, 2024. The unpublished version is available at the following link: https://public-inspection.federalregister.gov/2024-20814.pdf?utm_campaign=pi+subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov.

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6. Plagiarism	Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.	<p>Plagiarism also 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.</p> <p>Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.</p>
7. Subsequent Use Exception	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 (the " Subsequent Use Exception ").	Triggering of the Subsequent Use Exception requires a citation to the portion(s) of the research record (e.g., processed data, journal articles, funding proposals, data repositories) alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent.
8. Confidentiality	Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who "need to know."	Those who "need to know" may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. The limitation on disclosure of the identity of respondents, complainants, and witnesses explicitly no longer applies once an institution has made a final determination of research misconduct findings.
9. Respondent Record Retention	The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct if the respondent failed to maintain, failed to produce, or destroyed the records.	Simple failure to maintain adequate records is no longer sufficient to provide evidence of research misconduct. In order for the lack of research records to be evidence of research misconduct, the respondent had to have destroyed them or refused to provide them.

Topic	Current Rule¹	Final Rule²
10. Interview Transcripts	Interviews at the investigation stage must be transcribed, and the transcription must be provided to the interviewee for correction. The transcript should be maintained in the record of the investigation.	In addition, the respondent must be provided access to all transcripts.
11. Sequestration	Institutions must 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.”	When original research records cannot be obtained, copies of records that are “substantially equivalent in evidentiary value” will fulfill the sequestration requirement. Institutions may also sequester research records and evidence whenever additional items become known or relevant to the inquiry or investigation.
12. Finality of Institutional Decisions	Contains no clear statement that an institution’s determination of whether research misconduct occurred is independent of any finding from ORI regarding research misconduct. The lack of an explicit statement regarding the finality of an institution’s research misconduct finding has led to confusion among institutions and some arguments from respondents that a finding from ORI is required before a finding of research misconduct can be final.	Clarification that ORI findings are not required for institutional decisions regarding research misconduct to be considered final and to warrant “remediation under the institution’s policy.”
13. Multiple Respondents	Silent.	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.
14. Multiple Institutions	Silent.	When multiple institutions are involved in a research misconduct proceeding, one institution should be designated as the “lead institution.” The lead institution should obtain the research records from other relevant institutions.

Topic	Current Rule ¹	Final Rule ²
15. Institutional Records	Institution must file the investigation report with ORI at the conclusion of the investigation.	Institution must file <u>the entire institutional record</u> with ORI upon the conclusion of the investigation (including documentation of the assessment; the inquiry report and all records considered or relied on during the inquiry; the investigation report and all records considered or relied on during the investigation; all transcripts; decisions by the Institutional Deciding Official; records of any appeals; an index listing all the research records and evidence that the institution compiled during the research misconduct proceeding; and a general description of the records that were sequestered but not considered or relied on).