GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Generative Artificial Intelligence

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
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Table of Contents

Overview 4
Regulatory Considerations-Findings of Research Misconduct 4
Accepted Practices of the Relevant Research Community 4
Preponderance of the Evidence 5
Fabrication, Falsification, and Plagiarism 6
General Guidance on Disclosure of Generative AI Use 6
Honest Error Related to Allegations of Falsification or Fabrication 6
Fabricated Citations 6
Plagiarism 6
Institutional Policies 7
Pertinent Sections of 42 CFR Part 93 (2024) 8
§ 93.103 Requirements for findings of research misconduct. 8
§ 93.105 Evidentiary standards. 8
§ 93.200 Accepted practices of the relevant research community. 8
§ 93.211 Fabrication. 8
§ 93.212 Falsification. 9
§ 93.227 Plagiarism. 9
§ 93.228 Preponderance of the evidence. 9
§ 93.236 Research record. 9
§ 93.307 Institutional inquiry. 9
§ 93.310 Institutional investigation. 11
§ 93.318 Retention and custody of the institutional record and all sequestered evidence. 12
§ 93.408 Mitigating and aggravating factors in HHS administrative actions. 13

This guidance document is provided by the Office of Research Integrity (ORI) to assist entities that apply for or receive Public Health Service (PHS) funding for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training. It addresses generative artificial intelligence under the revised Public Health Service Policies on Research Misconduct regulation at 42 CFR Part 93 (2024). This guidance document does not create or confer rights for or on any person and does not operate to bind ORI, the Department of Health and Human Services, or the public. It also does not guarantee that ORI will find an institution compliant with 42 CFR Part 93. In case of any conflict between this document and 42 CFR Part 93, the regulation will prevail.

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Overview

In September 2024, the Department of Health and Human Services (HHS) updated its Public Health Service Policies on Research Misconduct regulation, 42 CFR Part 93, in part to address recent technological advancements. Generative artificial intelligence (AI) is one such advancement that has contributed to scientific breakthroughs and has the potential to contribute to many more. However, generative AI can also be misused, including in ways that constitute research misconduct. This document provides guidance to institutions as they navigate research misconduct proceedings involving generative AI.

In general, researchers and institutions should follow the same best practices during research misconduct proceedings regardless of whether generative AI tools are involved. Researchers should disclose any generative AI tools used during research and manuscript and grant preparation. Disclosure can protect against research misconduct allegations and support reproducibility. When evaluating allegations involving generative AI, institutional committees should gather and consider all available evidence. Institutional investigation committees must include persons with appropriate scientific expertise in the respondent's research field.[1] In cases involving generative AI, these experts can help establish whether alleged research misconduct involving generative AI use constitutes a significant departure from the accepted practices of the relevant research community.

Regulatory Considerations-Findings of Research Misconduct

Accepted Practices of the Relevant Research Community

A finding of research misconduct under 42 CFR Part 93 requires that there be a significant departure from the accepted practices of the relevant research community.[2] Research communities may vary in their perspectives on accepted practice, and institutions are responsible for determining whether a respondent's specific action significantly departs from the accepted practices of the relevant research community. Institutional committee members with appropriate scientific expertise in the respondent's research field can help establish whether a particular use of a generative AI tool falls within the accepted practices of the relevant research community.[3] Institutions could consider including subject matter experts in AI when creating inquiry and/or investigation committees to provide additional insight into the uses and functionality of generative AI tools associated with research misconduct allegations.[4]

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[1] 42 CFR § 93.310(f).
[2] §§ 93.103(a) and 93.200.
[3] Inquiry committees *may* include subject matter experts in the relevant research area, whereas investigation committees *must* include these experts. §§ 93.307(e)(2) and 93.310(f).
[4] *See* guidance on Institutional Committees at https://ori.hhs.gov/guidance-documents.

Preponderance of the Evidence

The regulation requires that a research misconduct allegation be proven by a preponderance of the evidence.[5] Institutional committees should consider all available types of evidence when carrying out research misconduct proceedings.[6] For example, evidence that suggests the questioned research could not have occurred as reported could be a strong indicator that the results are not genuine. Additionally, while the output from automated or AI-enabled tools that detect data manipulation or plagiarism may be evidence of research misconduct, ORI recommends against relying on such tools as the sole source of evidence during a research misconduct proceeding. Furthermore, institutions should be aware that plagiarism detection tools may have limited ability to detect plagiarized text in AI-generated scientific content such as proposals, reports, or manuscripts.

Experimental research often produces a forensic evidence trail. For example, the evidence could include purchasing records, intermediate files related to figure processing, or physical access logs for animal facilities. This evidence could help distinguish experimental research from synthetic or AI-enabled research, which may support or weaken a conclusion that the research occurred as described. Institutions and PHS funding components often have data retention policies that apply to researchers and may preserve the forensic trail. Institutions are encouraged to coordinate with their compliance units, such as institutional review boards and institutional animal care and use committees, to ensure institution-wide compliance with data retention policies and any other relevant laws, regulations, agreements, and ethical guidelines.

Under the updated regulation, a respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.[7] A respondent's destruction of research records documenting the questioned research is also evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations.[8] A respondent's failure to provide research records on request may also be an aggravating factor when HHS determines appropriate administrative actions.[9] Additionally, institutions must generally retain the institutional record, which typically includes research records, and all sequestered evidence for seven years after the completion of a research misconduct proceeding, including any HHS proceeding under subparts D and E of Part 93.[10]

[5] §§ 93.103(c) and 93.105. *See* § 93.228 (defining preponderance of the evidence).
[6] *See* guidance on Pursuing Leads at https://ori.hhs.gov/guidance-documents.
[7] § 93.105(b)(1).
[8] § 93.105(b)(1).
[9] § 93.408.
[10] § 93.318.

Fabrication, Falsification, and Plagiarism

General Guidance on Disclosure of Generative AI Use

Researchers should identify any generative AI tools used during their research and manuscript and grant preparation and explain how these tools were used. Clear identification of the tools as well as the steps taken to generate and process research data could potentially provide a defense against research misconduct allegations and support reproducibility in research by promoting understanding in the research community.

However, disclosing generative AI tool use does not necessarily preclude a research misconduct finding. If a researcher discloses use of a generative AI tool in a manner inconsistent with the accepted practices of the relevant research community, that use may still be considered evidence of research misconduct. Similarly, undisclosed or inaccurately described data generation or processing with AI tools may be evidence of data fabrication or falsification.[11] Researchers should verify all results, including those derived from processes involving generative AI.

Honest Error Related to Allegations of Falsification or Fabrication

Some commonly used tools include data preprocessing that researchers may not be aware of. For example, smartphone cameras may include automatic image alteration processes, a type of generative AI, and these cameras might be used to record research data. Respondents have the burden of proving honest error, including that a generative AI tool's alteration of research data constitutes honest error.[12]

Fabricated Citations

The regulatory definition of fabrication pertains to data or results.[13] References in publications and grant applications are not generally data or results because they do not arise from a publication's scientific inquiry.[14] Fabricated citations include those generated by AI tools but not reflecting real publications, which are often called hallucinated references. When references do not serve as data or results, fabricated citations may not constitute fabricated data or results.

However, in some cases, such as literature reviews, references are data because they arise from scientific inquiry. In these cases, fabricated citations could be the subject of research misconduct allegations.

Plagiarism

Plagiarism is the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.[15] Institutions must determine whether a respondent's use of AI-generated text or ideas constitutes plagiarism.

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[11] §§ 93.211 and 93.212.
[12] § 93.105(b)(2).
[13] § 93.211.
[14] § 93.236.
[15] § 93.227.

ORI's plagiarism policy explains that "ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work."[16] Generative AI tools can reproduce text or ideas from existing works and result in plagiarism. Therefore, researchers should determine whether text or ideas they use from generative AI tools have been copied from another person's work and cite those works appropriately.

Institutional Policies

ORI does not require institutional policies and procedures to address generative AI use. However, institutional policies addressing generative AI use may assist committee members as they adjudicate research misconduct cases by identifying practices that depart from the accepted practices of the relevant research community. Additionally, PHS funding agencies also maintain and are continuing to develop generative AI use policies. Institutions should be aware of these policies, because they may inform accepted practices in some research communities.

Technological advances such as generative AI tools hold great promise for research discoveries. Neither the updated regulation nor this guidance stymies that research. Instead, ORI aims to foster research integrity by promoting understanding of appropriate generative AI use in PHS-funded work.

ORI understands that concerns, uncertainties, and other issues occasionally emerge in the context of institutional management of research misconduct allegations. The institution's Research Integrity Officer (RIO) and other relevant institutional personnel are encouraged to contact ORI for technical assistance and/or attend a RIO Boot Camp, which ORI sponsors on a periodic basis. For more information on generative AI and research misconduct, please reach out to ORI at any time for guidance by calling (240) 453-8800 or emailing AskORI@hhs.gov.

[16] ORI Policy on Plagiarism, available at https://ori.hhs.gov/ori-policy-plagiarism.

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.103 Requirements for findings of research misconduct.

A finding of research misconduct made under this part requires that:

(a) There be a significant departure from accepted practices of the relevant research community; and

(b) The misconduct be committed intentionally, knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of the evidence.

§ 93.105 Evidentiary standards.

(a) *Standard of proof*. An institutional or HHS finding of research misconduct must be proved by a preponderance of the evidence.

(b) *Burden of proof*.

(1) The institution or HHS has the burden of proof for making a finding of research misconduct. A respondent's destruction of research records documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.

(2) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

(3) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, any mitigating factors relevant to a decision to impose administrative actions after a research misconduct proceeding.

§ 93.200 Accepted practices of the relevant research community.

Accepted practices of the relevant research community means those practices established by 42 CFR part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.

§ 93.211 Fabrication.

Fabrication means making up data or results and recording or reporting them.

§ 93.212 Falsification.

Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

§ 93.227 Plagiarism.

Plagiarism means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.

(a) 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.

(b) 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.

§ 93.228 Preponderance of the evidence.

Preponderance of the evidence means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

§ 93.236 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

§ 93.307 Institutional inquiry.

(a) *Criteria warranting an inquiry*. An inquiry is warranted if the allegation meets the following three criteria:

(1) Falls within the definition of research misconduct under this part;

(2) Is within the applicability criteria of § 93.102; and

(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(b) *Purpose*. An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry does not require a full review of the evidence related to the allegation.

(c) *Notice to the respondent*. At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. Only allegations specific to a particular respondent are to be included in the notification to that respondent. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

(d) *Sequestration of records*. An institution must obtain all research records and other evidence needed to conduct the research misconduct proceeding, consistent with § 93.305(a).

(e) *Conducting the inquiry—*

(1) *Multiple institutions*. A joint research misconduct proceeding must be conducted consistent with § 93.305(e).

(2) *Person conducting the inquiry*. Institutions may convene committees of experts to conduct reviews at the inquiry stage to determine whether an investigation is warranted. The inquiry review may be done by a RIO or another designated institutional official in lieu of a committee, with the caveat that if needed, these individuals may utilize one or more subject matter experts to assist them in the inquiry.

(3) *Interviews*. Institutions may interview witnesses or respondents that would provide additional information for the institution's review.

(f) *Inquiry results—*

(1) *Criteria warranting an investigation*. An investigation is warranted if:

(i) There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.102; and

(ii) Preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.

(2) *Findings of research misconduct*. Findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing, or reckless, cannot be made at the inquiry stage.

(g) *Inquiry report*.

(1) The institution must prepare a written report that meets the requirements of this section and § 93.309.

(2) If there is potential evidence of honest error or difference of opinion, the institution must note this in the inquiry report.

(3) The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.

(h) *Time for completion*.

(1) The institution must complete the inquiry within 90 days of its initiation unless circumstances warrant a longer period.

(2) If the inquiry takes longer than 90 days to complete, the inquiry report must document the reasons for exceeding the 90-day period.

§ 93.310 Institutional investigation.

Institutions conducting research misconduct investigations must:

(a) *Time*. Begin the investigation within 30 days after deciding an investigation is warranted.

(b) *Notice to ORI*. Notify ORI of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of §§ 93.307 and § 93.309.

(c) Notice to the respondent. Notify the respondent in writing of the allegation(s) within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins.

(1) The institution must give the respondent written notice of any allegation(s) of research misconduct not addressed during the inquiry or in the initial notice of investigation within a reasonable amount of time of deciding to pursue such allegation(s).

(2) If the institution identifies additional respondents during the investigation, the institution may but is not required to conduct a separate inquiry for each new respondent. If any additional respondent(s) are identified during the investigation, the institution must notify them of the allegation(s) and provide them an opportunity to respond consistent with this subpart.

(3) While an investigation into multiple respondents can convene with the same investigation committee members, separate investigation reports and research misconduct determinations are required for each respondent.

(d) *Sequestration of records*. Obtain all research records and other evidence needed to conduct the investigation, consistent with § 93.305(a).

(e) *Documentation*. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and other evidence relevant to reaching a decision on the merits of the allegation(s).

(f) *Ensuring a fair investigation*. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest relevant to the investigation. An institution may use the same committee members from the inquiry in their subsequent investigation.

(g) *Interviews*. During the investigation, an institution must interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent.

(1) Interviews during the investigation must be recorded and transcribed.

(2) Any exhibits shown to the interviewee during the interview must be numbered and referred to by that number in the interview.

(3) The transcript of the interview must be made available to the relevant interviewee for correction.

(4) The transcript(s) with any corrections and numbered exhibits must be included in the institutional record of the investigation.

(5) The respondent must not be present during the witnesses' interviews but must be provided a transcript of the interview.

(h) *Multiple respondents*. Consider, consistent with § 93.305(d), the prospect of additional researchers being responsible for the alleged research misconduct.

(i) *Multiple institutions*. A research misconduct proceeding involving multiple institutions must be conducted consistent with § 93.305(e).

(j) *Pursue leads*. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

§ 93.318 Retention and custody of the institutional record and all sequestered evidence.

(a) *Maintenance of institutional record and all sequestered evidence*. An institution must maintain the institutional record and all sequestered evidence including physical objects (regardless of whether the evidence is part of the institutional record) in a secure manner for seven years after completion of the proceeding or the completion of any HHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later, unless custody has been transferred to HHS under paragraph (b) of this section or ORI advises otherwise in writing.

(b) *Provision for HHS custody*. On request, institutions must transfer custody, or provide copies, to HHS of the institutional record or any component of the institutional record and any sequestered

evidence (regardless of whether the evidence is included in the institutional record) for ORI to conduct its oversight review, develop the administrative record, or present the administrative record in any proceeding under subparts D and E of this part.

§ 93.408 Mitigating and aggravating factors in HHS administrative actions.

The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct and the need to protect the health and safety of the public, promote the integrity of the PHS-supported research and research process, and conserve public funds. ORI considers the following aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. The existence or nonexistence of any factor is not determinative.

(a) *Knowing, intentional, or reckless*. Were the respondent's actions knowing or intentional or were the actions reckless?

(b) *Pattern*. Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?

(c) *Impact*. Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?

(d) *Acceptance of responsibility*. Has the respondent accepted responsibility for the misconduct by:

(1) Admitting the conduct;

(2) Cooperating with the research misconduct proceedings;

(3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and

(4) Taking steps to correct or prevent the recurrence of the research misconduct?

(e) *Failure to accept responsibility*. Does the respondent blame others rather than accepting responsibility for the actions?

(f) *Retaliation*. Did the respondent retaliate against complainants, witnesses, committee members, or other individuals?

(g) *Continued risk to PHS funding*. Does the respondent demonstrate responsible stewardship of research resources?

(h) *Other factors*. Are other factors relevant to the circumstances of a particular case?