GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Honest Error

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
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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 the topic of honest error according to 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). This regulation defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion."[1] PHS-supported biomedical and behavioral research is often complex, and honest errors can occur during the course of this work. An action that appears to be research misconduct may be honest error. During research misconduct proceedings, respondents sometimes assert that the alleged falsification, fabrication, or plagiarism resulted from honest error. It is important to understand the role of honest error in 42 CFR Part 93 and how making a determination of honest error influences a research misconduct proceeding.

Role of Honest Error

As noted above, the definition of research misconduct under 42 CFR Part 93 does not include honest error. If a respondent's actions were honest errors, those actions did not constitute research misconduct under Part 93. Institutions are not required to disprove possible honest error if no evidence of honest error exists or is introduced by a respondent. However, if there is evidence of honest error, regardless of whether such evidence is provided by a respondent, institutions must consider that evidence when determining whether a respondent's actions meet the definition of research misconduct.

If an institution has potential evidence of honest error at the inquiry stage, it must note the evidence in its inquiry report.[2] ORI recommends that institutions document in their inquiry or investigation reports how they considered evidence of honest error, with enough detail to permit ORI review of the institution's reasoning. If an institution determines at the inquiry or investigation stage that a respondent's actions were honest errors, and therefore the definition of research misconduct is not met, the institution may close the research misconduct proceeding under Part 93.

Considering Honest Error

When considering evidence of honest error, institutions should take into account the credibility and relevance of the evidence. An evaluation of the scope of the potential misconduct is also helpful to determine whether honest error occurred. ORI recommends that institutions follow these best practices when considering whether a respondent's actions were honest error:

- Reviewing the data in the respondent's research record to ascertain whether the respondent's practices are those established by the accepted practices of the relevant research community. The research record may include research proposals such as grant applications, raw data, processed data, clinical research records, laboratory records, study records, laboratory

[1] 42 CFR § 93.234.
[2] § 93.307(g)(2).

notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.[3]

- Reviewing the research record carefully to determine whether the honest error assertion is supported by the evidence provided by the respondent.
- Evaluating whether the alleged misconduct is a single occurrence or part of a pattern by conducting a scoping analysis including grant applications and published papers to identify any potential additional research misconduct.[4]
- Examining the specific experiment(s) and result(s) in question, to determine whether making an honest error is scientifically plausible. For instance, the committee could assess whether the results in question were altered. If there are numerous allegations, the committee could examine whether the majority of errors effectively changed the data to fit the hypothesis.
- Considering the respondent's actions and behaviors in context. For example:
    - The respondent readily admits to the mistake when responding to the allegation(s) but makes no attempt to explain how the alleged error occurred.
    - The respondent seems to have a poor understanding of the science in question, whether researchers could easily have made the same error, under the given circumstances.
    - The respondent took reasonable steps to correct the data and/or ensure the accuracy of the questioned research.

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 honest error, please reach out to ORI at any time for guidance by calling (240) 453-8800 or emailing AskORI@hhs.gov.

[3] § 93.236.
[4] *See* ORI guidance on Pursuing Leads at https://ori.hhs.gov/guidance-documents.

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.234 Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

§ 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.