GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Institutional Assessments

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 institutional assessments 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). The updated regulation describes the assessment phase of research misconduct proceedings and institutions' obligations with regard to conducting and documenting the assessment.

The purpose of an assessment is to determine whether an allegation warrants an inquiry.[1] When the Research Integrity Officer (RIO) or other designated institutional official receives an allegation of research misconduct they must promptly determine whether the allegation meets the criteria for an institutional inquiry.[2] These criteria are met if the research misconduct allegation:

- Appears to fall within the PHS definition of research misconduct, which is defined at 42 CFR § 93.234 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);
- Appears to meet the applicability criteria of 42 CFR § 93.102 by involving PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; activities, or records and
- Is specific and credible so that the potential evidence relevant to the allegations of research misconduct may be identified.[3]

As with all stages of the misconduct proceeding, the RIO should keep in mind the institution's duty to maintain the confidentiality of both complainants (aka "whistleblowers") and the respondent.[4]

Assessing Allegations

The RIO should promptly assess the allegation by reviewing only readily accessible and relevant information.[5] This may include conducting an informal interview with the complainant, if appropriate. Due to the requirement to notify the respondent and sequester relevant data upon making a determination to proceed to an inquiry, the assessment phase does not involve interviewing the respondent.

The RIO may find that the allegation involves misconduct other than fabrication, falsification, or plagiarism (such as harassment, bullying, fraud, or the mistreatment of human or animal research subjects) or does not involve an application for or receipt of PHS support, as described in § 93.102(b). Such allegations fall outside the scope of 42 CFR Part 93. The RIO should adhere to the institution's applicable reporting obligations and refer any such allegations to the appropriate institutional official or

[1] 42 CFR § 93.306(a).
[2] § 93.306(b).
[3] §§ 93.204 and 93.306(b).
[4] § 93.300(e).
[5] § 93.204.

federal, state, or local oversight body. The RIO should also consider when the alleged research misconduct occurred, as the updated regulation applies a time limit for addressing research misconduct allegations; however, the updated regulation provides an exception to this time limit for subsequent use and the institution must examine each allegation to determine whether the subsequent-use exception applies.[6]

Some allegations of research misconduct involve multiple institutions. For such cases, the assessment period provides an opportunity to coordinate with other institutions prior to sequestration of evidence and notification to the respondent, in accordance with the respective institutions' regulations and applicable institutional policies.[7]

To determine whether an allegation is sufficiently credible and specific to warrant moving to an inquiry, the RIO may need to review evidence during the assessment. However, the RIO should limit the scope of the review to readily accessible information and take great care to maintain confidentiality. The RIO should also avoid contact with the respondent to help ensure the fidelity of potential evidence. It is important to keep in mind that sequestering evidence and notifying the respondent occur during the institutional inquiry, the stage of misconduct proceedings following the institutional assessment.[8] Accordingly, during the assessment, the RIO may identify potential evidence and consider the practical arrangements needed to sequester it once the decision is made to move to an inquiry.

Documenting Assessments

The updated regulation specifies that institutions must document the assessment process to permit a later review by ORI of the reasoning behind their determination, particularly if they decide not to proceed to an inquiry.[9] Pertinent details may include:

- The complainant and respondent names and position titles;
- Content of the allegations;
- PHS funding sources, proposals, research, or activities; and
- A sufficiently detailed justification of the decision not to proceed to an inquiry.

The institution's documentation of the assessment becomes part of the institutional record.[10] 42 CFR Part 93 requires institutions to secure and retain the institutional record for seven years after completion of the proceedings.[11] At any point, institutions may be asked to transfer custody of this documentation to ORI for oversight review.[12]

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[6] *See* ORI guidance on Subsequent Use Exception at https://ori.hhs.gov/guidance-documents.
[7] *See* ORI guidance on Multiple Institutions at https://ori.hhs.gov/guidance-documents.
[8] § 93.307.
[9] § 93.306(c).
[10] § 93.220(a)(1).
[11] § 93.318.
[12] *See* ORI guidance on Institutional Records and Administrative Records at https://ori.hhs.gov/guidance-documents.

Separating Assessments from Inquiries

The purpose of the assessment is to determine whether an allegation warrants an inquiry.[13] An inquiry is warranted when the RIO (or another designated institutional official) determines, from a review of readily accessible information, that the allegation appears to meet the part 93 definition of research misconduct, appears to be within the applicability criteria of § 93.102, and is sufficiently specific and credible so that potential evidence of research misconduct can be identified.[14] If these criteria are met, the RIO should promptly sequester all relevant research records and other evidence and initiate the inquiry.[15]

Thus, the assessment phase requires that institutions conduct an initial screening of an allegation that is separate from the increasingly detailed consideration of an allegation that occurs during institutional inquiries and investigations. During the institutional inquiry, an initial review of the sequestered evidence should be conducted to determine whether an allegation warrants an investigation.[16] An inquiry does not require a full review of the evidence related to the allegation, which occurs during the investigation stage.[17] This separation of the assessment from other parts of research misconduct proceedings helps to conserve institutional resources and can protect the reputation of the respondent if the assessment does not proceed to an inquiry.

ORI understands that concerns, uncertainties, and other issues occasionally emerge in the context of institutional management of research misconduct allegations. The institution's 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 assessments, please reach out to ORI at any time for guidance by calling (240) 453-8800 or emailing AskORI@hhs.gov.

[13] § 93.306(a).
[14] §§ 93.204 and 93.306(b).
[15] § 93.306(c)(2)(ii).
[16] An investigation is warranted when "preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance" and "there is a reasonable basis for concluding that the allegation" falls with the PHS definition of research misconduct and involves PHS support. § 93.307(f).
[17] § 93.307(b).

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.204 Assessment.

Assessment means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.

§ 93.220 Institutional record.

The institutional record comprises:

(a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include, but are not limited to:

(1) Documentation of the assessment as required by § 93.306(c).

(2) If an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c).

(3) If an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution.

(4) Decision(s) by the Institutional Deciding Official, such as the written decision from the Institutional Deciding Official under § 93.314.

(5) The complete record of any institutional appeal consistent with § 93.315.

(b) A single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on.

(c) A general description of the records that were sequestered but not considered or relied on.

§ 93.306 Institutional assessment.

(a) *Purpose.* An assessment's purpose is to determine whether an allegation warrants an inquiry.

(b) *Conducting the institutional assessment.* Upon receiving an allegation of research misconduct, the RIO or another designated institutional official must promptly assess the allegation to determine whether the allegation:

(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.

(c) *Assessment results.* (1) An inquiry must be conducted if the allegation meets the three assessment criteria in paragraph (b) of this section.

(2) If the RIO or another designated institutional official determines that requirements for an inquiry are met, they must:

(i) Document the assessment; and

(ii) Promptly sequester all research records and other evidence, consistent with § 93.305(a), and promptly initiate the inquiry.

(3) If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they must keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why the institution did not conduct an inquiry. Such documentation must be retained in accordance with § 93.318.

§ 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.

§ 93.318 Retention and custody of the institutional record and 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.