GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Institutional Records

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Research Integrity (ORI)
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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 records 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 updated regulation defines the institutional record, which is critical to institutional research misconduct proceedings and ORI's oversight review.

The institutional record for a research misconduct proceeding typically includes reports, research records, and other documents and information compiled or generated during the research misconduct proceeding.[1]

ORI uses the institutional record to conduct oversight of institutional proceedings.[2] ORI also uses the institutional record to determine whether to close the case without further action or proceed with the case.[3] If ORI proceeds with the case, the institutional record becomes a key part of the administrative record that ORI compiles to support its decision-making.[4]

Components of the Institutional Record

As defined in 42 CFR § 93.220, the institutional record has three components:

1. Records the institution compiled or generated during the research misconduct proceeding, except those the institution did not consider or rely on. These records include, but are not limited to:
    a. Documentation of the assessment as required by § 93.306(c).
    b. 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 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).
    c. 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.
    d. Written decision(s) by the Institutional Deciding Official under § 93.314.
    e. The complete record of any institutional appeal consistent with § 93.315.

2. 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.

[1] 42 CFR § 93.220.
[2] §§ 93.400(a)(6) and 93.403(a).
[3] § 93.403(a)(4).
[4] §§ 93.202, 93.404(a), 93.500(c), 93.504(a), and 93.511(a).

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

Transmission to ORI

Below is a summary of when an institution must provide the institutional record or portions of the institutional record to ORI:

- After an assessment is completed, the institution must provide assessment documentation to ORI *upon request*.[5]
- After an inquiry is completed, if the institution determines an investigation is warranted, it must provide ORI a copy of the inquiry report within 30 days of that determination.[6] If the institution determines an investigation is not warranted, it must provide inquiry documentation to ORI *upon request*.[7] Regardless of whether an institution determines an investigation is warranted, the institution must provide research records and other evidence reviewed, and copies of all relevant documents to ORI, *upon request*.[8]
- After an investigation is completed and the Institutional Deciding Official has made a final determination of research misconduct findings in accordance with § 93.314, the institution must transmit the entire institutional record to ORI.[9]
- After the institution has transmitted its institutional record to ORI in accordance with § 93.316, if the respondent appeals an institution's finding(s) of research misconduct or institutional actions, the institution must provide ORI a complete record of the appeal once the appeal is concluded.[10]

ORI reminds institutions of the general requirement to transfer custody (or provide copies) to HHS of the institutional record or any component of the institutional record and any sequestered evidence upon request, as explained in more detail in 93.318(b).

ORI's Oversight Review

ORI will conduct an oversight review of the institutional record transmitted under § 93.316 to determine whether it is sufficient.[11] In this review, ORI will consider whether the institutional record is logically organized and includes all components required by 93.220.[12] ORI will evaluate whether the institution conducted its proceedings in a timely and fair manner in accordance with 42 CFR Part 93 with sufficient thoroughness, objectivity, and competence to support the conclusions.[13]

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[5] §§ 93.306(c) and 93.318(b).
[6] § 93.309(a).
[7] §§ 93.309(c) and 93.318(b).
[8] §§ 93.309(b)(2) and 93.318(b).
[9] § 93.316.
[10] § 93.315(c).
[11] §§ 93.400(a)(6) and 93.403(a)(2).
[12] § 93.316.
[13] § 93.403(a)(3).

As part of its oversight review, ORI will provide instructions to the institution if ORI determines that revisions are needed or additional allegations of research misconduct should be addressed and require institutions to provide the respondent with an opportunity to respond to information or allegations added to the institutional record.[14]

Maintenance of the Institutional Record and Sequestered Evidence

Institutions 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 the completion of the institutional proceeding or any HHS proceeding involving the research misconduct allegation under 42 CFR Part 93, subparts D and E, whichever is later, unless custody has been transferred to HHS or ORI advises otherwise in writing.[15]

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

[14] § 93.403(a)(2).
[15] § 93.318.

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.202 Administrative record.

Administrative record comprises: the institutional record; any information provided by the respondent to ORI, including but not limited to the transcript of any virtual or in-person meetings under § 93.403(b) between the respondent and ORI, and correspondence between the respondent and ORI; any additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the respondent.

§ 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.

§ 93.309 Reporting to ORI on the decision to initiate an investigation.

(a) Within 30 days of determining that an investigation is warranted, the institution must provide ORI with a copy of the inquiry report, which includes the following information:

(1) The names, professional aliases, and positions of the respondent and complainant;

(2) A description of the allegation(s) of research misconduct;

(3) The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;

(4) The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise;

(5) Inventory of sequestered research records and other evidence and description of how sequestration was conducted;

(6) Transcripts of any transcribed interviews;

(7) Timeline and procedural history;

(8) Any scientific or forensic analyses conducted;

(9) The basis for recommending that the allegation(s) warrant an investigation;

(10) The basis on which any allegation(s) do not merit an investigation;

(11) Any comments on the inquiry report by the respondent or the complainant; and

(12) Any institutional actions implemented, including communications with journals or funding agencies.

(b) The institution must provide the following information to ORI whenever requested:

(1) The institutional policies and procedures under which the inquiry was conducted; and

(2) The research records and other evidence reviewed, and copies of all relevant documents.

(c) Institutions must keep detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to investigate. Such documentation must be retained in accordance with § 93.318.

(d) In accordance with § 93.305(g), institutions must notify ORI of any special circumstances that may exist.

§ 93.315 Institutional appeals.

(a) If a respondent appeals an institution's finding(s) of research misconduct or institutional actions, the institution must promptly notify ORI.

(b) If the institution has not transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must wait until the appeal is concluded to transmit its institutional record. The institution must ensure that the complete record of the appeal is included in the institutional record consistent with § 93.220(a)(5).

(c) If the institution has transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must provide ORI a complete record of the appeal once the appeal is concluded.

§ 93.316 Transmittal of the institutional record to ORI.

After the Institutional Deciding Official has made a final determination of research misconduct findings in accordance with § 93.314, the institution must transmit the institutional record to ORI. The institutional record must be consistent with § 93.220 and logically organized.

§ 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.

§ 93.400 General statement of ORI authority.

(a) *ORI review.* ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter. The ORI response may include but is not limited to:

(1) Conducting allegation assessments;

(2) Determining independently whether jurisdiction exists under this part;

(3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;

(4) Requesting clarification or additional information, documentation, research records, or other evidence as necessary from an institution or its members or other persons or sources to carry out ORI's review;

(5) Notifying or requesting assistance and information from PHS funding components, other affected Federal and state offices and agencies, or institutions;

(6) Reviewing the institutional record and directing the institution to address deficiencies or additional allegations in the institutional record;

(7) Making a finding of research misconduct; and

(8) Taking actions as necessary to protect the health and safety of the public, to promote the integrity of PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, or to conserve public funds.

(b) *ORI assistance to institutions.* ORI may:

(1) Provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's research misconduct proceedings and the sufficiency of the institutional record; and

(2) Issue guidance and provide information to support institutional implementation of and/or compliance with the requirements of this part.

(c) *Review of institutional research integrity assurances.* ORI will review institutional research integrity assurances and policies and procedures for compliance with this part.

(d) *Institutional compliance.* ORI may make findings and impose ORI compliance actions related to an institution's compliance with this part and with its policies and procedures, including an institution's participation in research misconduct proceedings.

§ 93.403 ORI review of research misconduct proceedings.

(a) In conducting its review of research misconduct proceedings, ORI will:

(1) Determine whether this part applies;

(2) Consider the institutional record and determine whether the institutional record is sufficient, provide instructions to the institution(s) if ORI determines that revisions are needed or additional allegations of research misconduct should be addressed, and require institutions to provide the respondent with an opportunity to respond to information or allegations added to the institutional record;

(3) Determine whether the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions; and

(4) After reviewing in accordance with paragraphs (a)(1) through (3) of this section, determine whether to close the case without further action or proceed with the case.

(b) If ORI determines to proceed with the case, ORI will:

(1) Obtain additional information or materials from the institution, the respondent, complainants, or other sources, as needed;

(2) Conduct additional analyses, as needed;

(3) Provide the respondent the opportunity to access the institutional record, any additional information provided to ORI while the case is pending before ORI, and any analysis or additional information generated or obtained by ORI;

(4) Provide the respondent the opportunity to submit information to ORI;

(5) Allow the respondent and the respondent's attorney, if represented, to meet virtually or in person with ORI to discuss the information that the respondent has provided to ORI;

(6) Have ORI's virtual or in-person meeting(s) with the respondent transcribed and provide a copy of the transcript to the respondent for review and suggested correction;

(7) Close the administrative record following paragraphs (b)(3) through (6) of this section;

(8) Provide the respondent the opportunity to access the complete administrative record; and

(9) Take any other actions necessary to complete ORI's review of the research misconduct proceedings.

§ 93.404 Findings of research misconduct and proposed HHS administrative actions.

(a) After completing its review of the administrative record, ORI may:

(1) Close the case without a separate ORI finding of research misconduct;

(2) Make findings of research misconduct and propose and take HHS administrative actions based on the administrative record; or

(3) Seek to settle the case.

(b) The lack of an ORI finding of research misconduct does not overturn an institution's determination that the conduct constituted professional or research misconduct warranting remediation under the institution's policy.

§ 93.500 General policy.

(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and/or proposed HHS administrative actions included in a charge letter.

(b) A respondent may contest ORI's research misconduct findings and proposed HHS administrative actions by filing a notice of appeal with an Administrative Law Judge (ALJ) at the DAB.

(c) Based on the administrative record, the ALJ shall rule on whether ORI's research misconduct findings and any proposed HHS administrative actions are reasonable and not based on a material error of law or fact. The ALJ's ruling constitutes a recommended decision to the Assistant Secretary for Health (ASH) in accordance with § 93.511(b).

(d) A respondent must exhaust all available administrative remedies under this subpart before seeking judicial review of ORI's findings and/or HHS administrative actions. The contested findings and/or administrative actions shall be inoperative while the respondent is pursuing administrative remedies under this subpart.

§ 93.504 Standard of review.

(a) The ALJ shall review the administrative record to determine whether the ORI research misconduct findings and proposed HHS administrative actions reflected in the charge letter are reasonable and not based on a material error of law or fact.

(b) The ALJ may permit the parties to file briefs making legal and factual arguments based on the administrative record.

§ 93.511 The Administrative Law Judge's ruling.

(a) Based on the administrative record, the ALJ shall issue a ruling in writing within 60 days after the last submission by the parties in the case, setting forth whether ORI's research misconduct findings and proposed HHS administrative actions reflected in the charge letter are reasonable and not based on

a material error of law or fact. If the ALJ is unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties. The ALJ shall serve a copy of the ruling upon the parties and the ASH.

(b) The ruling of the ALJ constitutes a recommended decision to the ASH. The ASH may review the ALJ's recommended decision and adopt, modify, or reject it (in whole or in part) as needed to ensure that the decision is reasonable and not based on a material error of law or fact. Within 30 days after service of the ALJ's recommended decision, the ASH shall notify the parties of the ASH's intent to review or not to review the ALJ's recommended decision. If the ASH does not provide notice of intent within the 30-day period or notifies the parties that the ASH does not intend to review the ALJ's recommended decision, the ALJ's recommended decision shall become final. An ALJ's recommended decision that becomes final in that manner or the ASH's decision after review constitutes the final HHS action on both ORI's findings of research misconduct and any HHS administrative actions.