GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Institutional Record Best Practices

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 institutional record best practices 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). As defined in the updated regulation at 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;
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; and
3. A general description of the records that were sequestered but not considered or relied on.

The records the institution compiled or generated during the research misconduct proceeding include, but are not limited to:

- Documentation of the assessment as required by § 93.306(c);
- Inquiry report(s) 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);
- Investigation report(s) 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;
- Decision(s) by the Institutional Deciding Official, such as the written decision from the Institutional Deciding Official under § 93.314; and
- The complete record of any institutional appeal consistent with § 93.315.

42 CFR Part 93 also requires that the institutional record be logically organized when transmitted to ORI.[1] ORI developed the following best practices to help institutions compile and organize the institutional record. For ORI to conduct its oversight review, develop the administrative record, and present the administrative record in any appeal, the institution must submit the complete institutional record to ORI.[2] The institutional record includes the written decision from the Institutional Deciding Official.

Best Practices

ORI reviews the institutional record when conducting its oversight of institutional research misconduct proceedings. Additionally, the institutional record becomes part of the administrative record, which ORI develops and files in any administrative appeal before an administrative law judge (ALJ) under subpart E of 42 CFR Part 93.[3]

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[1] 42 CFR Part § 93.316.

[2] Institutions must also submit any sequestered evidence, regardless of whether the evidence is included in the institutional record, on ORI's request. § 93.318.

[3] §§ 93.202 and 93.503. *See* guidance on the Institutional Record at https://ori.hhs.gov/guidance-documents.

Creating an Index

The institutional record includes a single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except those the institution did not consider or rely on.[4]

ORI recommends that institutions begin to create this index at the start of the proceeding. As each stage of the proceeding (i.e., assessment, inquiry, investigation) progresses, institutions may add any research records and evidence that they consider or rely on to the index.[5] ORI recommends that the index include separately numbered entries for each record or other evidence, as well as a brief description for each entry. See appendix for a sample index.

ORI recommends short file names containing 25 characters or fewer. Including the case index number in the file name is not necessary. Institutions can use abbreviations and shorthand and then expand on file names in the index.

Institutions can refer to the index as the proceeding progresses, so the same research records and evidence are consistently identified across documents such as the inquiry report and investigation report to facilitate compliance with § 93.310(g)(2).

The Institutional Record Transmittal Form

Institutions should submit the Institutional Record Transmittal form (PHS-7092) with the institutional record to ORI at the conclusion of research misconduct proceedings. Institutions should submit PHS-7092 to ORI regardless of whether the case falls under the 2005 or 2024 version of 42 CFR Part 93. If ORI during its oversight review directs the institution to address deficiencies in the institutional record, it is not necessary for the institution to resubmit the form unless ORI requests it. If the proceedings conclude at the assessment, institutions do not need to submit PHS-7092.

General Description of Sequestered Research Records and Evidence

The institutional record includes a general description of the records that were sequestered but not considered or relied on.[6] The general description requirement does not require identification of specific files or emails but allows for a broader summary of the types of files or emails sequestered (e.g., research technician's lab notebooks, forensic copy of respondent's hard drive).

ORI recommends that institutions inventory all research records and other evidence as soon as they are sequestered.[7] Institutions may use the inventory, in conjunction with the index required under § 93.220(b), to identify records that were sequestered but not considered or relied on.

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[4] § 93.220(b).
[5] Please note that § 93.306 does not require a formal assessment report but does require the institution to document the assessment for the institutional record.
[6] § 93.220(c).
[7] See ORI guidance on Sequestration at https://ori.hhs.gov/guidance-documents. See also ORI tips on sequestration and handling of evidence: https://ori.hhs.gov/tips-sequestration-physical-evidence-research-misconduct-cases and https://ori.hhs.gov/tips-handling-physical-evidence-research-misconduct-cases.

Please note, the general description and the index are two separate documents. The index should include evidence the institution considered or relied on during the research misconduct proceeding. The general description, on the other hand, includes evidence that the institution did not consider or rely on during the proceeding.

Transmitting the Institutional Record to ORI

ORI recommends that institutions transmit their institutional records to ORI using Box.com (also known as the ORI File Transfer System or ORI-FTS). It may be helpful to use the following folder structure to organize the record, as applicable:

- A: Transmittal form
- B: Documentation of assessment
- C: Inquiry report with accompanying records
- D: Investigation report with accompanying records
- E: Decision(s) by the Institutional Deciding Official
- F: Indexed research records and evidence, except records the institution did not consider or rely on
    - Index document
    - Research records/evidence
- G: General description of records that were sequestered but not considered or relied on
- H: Institutional appeal record

Overall, the institutional record should be logically organized and include the records, index, and general description as explained in 42 CFR § 93.220.

ORI requests that institutions submit each of the documents in the institutional record as a separate PDF file. For example, the investigation report would be one PDF file, and each of the attachments to the investigation report would be separate PDF files. If a record cannot be in PDF format, for example, if it is a video recording or a native file with metadata, institutions can insert a PDF slipsheet in place of that record identifying it as a placeholder for the native file and forward the native file to ORI labeled with the index entry number. Receiving the institutional record in PDF format will facilitate ORI's oversight review and help streamline the agency appeal process under subpart E.

If an institution has any issues related to submitting the institutional record, please contact ORI.

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

Sample Index of Research Records and Evidence

This is an example of what an index of research records and evidence can look like when an institution submits the institutional record to ORI.

Entry Number	Description	Notes (optional)
1	Month/day/year Allegation email	
2	Grant number	
3	Grant progress report (such as Research Performance Progress Report)	
4	Journal article	
5	Western blot files	
6	PPT from respondent	
7	Month/day/year Email from respondent to first author	
8	Image analysis	
9	Month/day/year Respondent interview recording	
10	Month/day/year Respondent interview transcript	
11	Month/day/year Respondent submission of information	

Institutions can include additional columns to reflect information appropriate for the proceeding, e.g., primary author or creator, file format, and/or additional notes.

Institutions remain free to use a different format or content, provided they create a single index listing all the research records and evidence compiled during the research misconduct proceeding, except records the institution did not consider or rely on.

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.

§ 93.310 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.

§ 93.316 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.

§ 93.503 Filing of the administrative record.

(a) For appeals that are not dismissed under § 93.502(a), ORI will file the administrative record for the appeal.

(b) The ALJ's review will be based on the administrative record.

(c) The parties have no right to supplement the administrative record.