GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Research 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 research 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). The updated regulation provides considerable detail regarding what constitutes research records. PHS-supported institutions span a wide range of settings and conduct a wide range of research across the biomedical and behavioral sciences, and their research records may be in a variety of forms and formats.

42 CFR Part 93 specifies that, once institutions determine that an allegation warrants an inquiry, they must promptly take all reasonable and practical steps to obtain all research records and other evidence needed to conduct the research misconduct proceeding.[1] Further, this regulation defines a research record as, "the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form."[2]

The regulation provides examples of items, materials, or information that may be considered part of the research record that 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, journal articles, published papers, PHS grant applications, presentations, and posters.[3]

When a research misconduct allegation proceeds to an inquiry, institutions must promptly take all reasonable and practical steps to obtain all research records and other evidence needed to conduct the research misconduct proceeding; inventory the research records and other evidence; and sequester them in a secure manner. When research records or other types of evidence are located on or encompass scientific instruments shared by multiple users, institutions may obtain copies of the data or other evidence from the instruments if those copies are substantially equivalent in evidentiary value to the source data.[4] In other words, copies are acceptable if they are substantially equivalent in evidentiary value to the information on the shared equipment. For example, copies of files should retain the same file structure and metadata, which ORI may need to review later when conducting its regulatory oversight.

When conducting its regulatory oversight of an institution's proceedings, ORI reviews records generated by the institution during the proceedings and the research records the institution considered or relied on.[5] Ideally, the research records should enable a reviewer to independently and accurately track a given scientific image or experimental result back to the allegedly fabricated, falsified, or plagiarized data in question. A reviewer should be able to identify source data and follow how a questioned research figure or image was created.

[1] 42 CFR §§ 93.305(a) and 93.306(c)(2)(ii).
[2] § 93.236.
[3] §§ 93.236 and 93.313(g).
[4] § 93.305(a).
[5] §§ 93.400(a) and 93.403(a).

Identifying Research Records

When institutions initiate research misconduct proceedings and pursue leads, institutions may need to sequester research records such as:

- forensic copies of computer hard drives
- physical or electronic equipment
- laboratory notebooks noting sample preparation and order
- proprietary source files
- graphing software and files
- laboratory equipment and hard drives shared between laboratories or within departments
- orders and results from core facilities used to outsource experiments or data analyses

Raw data may be of particularly important evidentiary value during research misconduct proceedings. Raw data is comprised of a researcher's primary observations that have not been processed or modified after the readings were made. Sequestered evidence should include whatever the researcher used to generate data, document results, and draw conclusions. This evidence may include but is not limited to spreadsheets, graphing and statistics files, figure images, or evidence collected from scientific instruments.

Raw data files should include the associated metadata, not just a screenshot or other replica. Specialized equipment or software may be required to access relevant content. ORI prefers this level of detail because many biomedical images are digitized and captured using proprietary software, and these files may have metadata and other useful information. For example, discrepancies between a source data file and a final illustration may indicate potential falsification or fabrication of the data.

Laboratory and Clinical Research Records

If the allegedly falsified, fabricated, or plagiarized data is from laboratory or clinical studies, the sequestered research records should include an audit trail of data or results from the beginning of the study to its conclusion. For example, data or results may include materials produced across the research lifecycle from collection to analysis and publication. If the questioned data is reported in a published document, such as an article or grant proposal, the complete research record may also include relevant unpublished documents that are still under consideration by publishers and funders.

When alleged research misconduct involves clinical research, relevant research records may include:

- regulatory binders,
- research-subject files,
- original source documents,
- case report forms sent to sponsor,
- human-subject medical records that include research related data,
- communications between the funding agency and members of the research team,
- Data Safety and Monitoring Board reports, and/or

- Drug or Device Accountability Logs.

When alleged research misconduct involves clinical research, relevant research records may be subject to privacy laws or other legal protections. ORI recommends that before sequestering evidence in a clinical research setting, institutions consult with their legal counsel to ensure compliance with all applicable legal requirements.

This guidance document provides examples of what may constitute research records in a research misconduct proceeding, and other types of research records not listed here may apply to a specific case. Whatever form the records take, it is incumbent on the institution to identify, sequester, secure, inventory, and consider all relevant evidence.[6] It is important for the institution to maintain the chain of custody by documenting who is responsible for the records and where they are being secured, from the moment of sequestration, throughout the proceedings, and during the required retention period.[7]

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

[6] § 93.305(a).
[7] § 93.318(a).

Pertinent Sections of 42 CFR Part 93 (2024)

§ 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.

§ 93.305 General conduct of research misconduct proceedings.

(a) *Sequestration of research records and other evidence*. An institution must promptly take all reasonable and practical steps to obtain all research records and other evidence, which may include copies of the data or other evidence so long as those copies are substantially equivalent in evidentiary value, needed to conduct the research misconduct proceeding; inventory the research records and other evidence; and sequester them in a secure manner. Where the research records or other evidence are located on or encompass scientific instruments shared by multiple users, institutions may obtain copies of the data or other evidence from such instruments, so long as those copies are substantially equivalent in evidentiary value to the instruments. Whenever possible, the institution must obtain the research records or other evidence:

(1) Before or at the time the institution notifies the respondent of the allegation(s); and

(2) Whenever additional items become known or relevant to the inquiry or investigation.

(b) *Access to research records*. Where appropriate, an institution must give the respondent copies of, or reasonable supervised access to, the research records that are sequestered in accordance with paragraph (a) of this section.

(c) *Maintenance of sequestered research records and other evidence*. An institution must maintain the sequestered research records and other evidence as required by § 93.318.

(d) *Multiple respondents*. If an institution identifies additional respondents during an inquiry or investigation, the institution is not required to conduct a separate inquiry for each new respondent. However, each additional respondent must be provided notice of and an opportunity to respond to the allegations, consistent with this subpart.

(e) *Multiple institutions*. When allegations involve research conducted at multiple institutions, one institution must be designated as the lead institution if a joint research misconduct proceeding is conducted. In a joint research misconduct proceeding, the lead institution should obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry

and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

(f) *Using a committee, consortium, or other person for research misconduct proceedings*.

(1) An institution must address any potential, perceived, or actual personal, professional, or financial conflicts of interest between members of the committee or consortium, or other person, and the complainant, respondent, or witnesses.

(2) An institution must ensure that a committee, consortium, or person acting on its behalf conducts research misconduct proceedings in compliance with the requirements of this part.

(g) *Notifying ORI of special circumstances*. At any time during a research misconduct proceeding, as defined in § 93.235, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

(1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(2) HHS resources or interests are threatened.

(3) Research activities should be suspended.

(4) There is reasonable indication of possible violations of civil or criminal law.

(5) Federal action is required to protect the interests of those involved in the research misconduct proceeding.

(6) HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

§ 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.

§ 93.313 Investigation report.

A final investigation report for each respondent must be in writing and include:

(a) Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.

(b) Description and documentation of the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.

(c) Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.

(d) Composition of investigation committee, including name(s), position(s), and subject matter expertise.

(e) Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation. This inventory must include manuscripts and funding proposals that were considered or relied on during the investigation.

(f) Transcripts of all interviews conducted, as described in § 93.310(g).

(g) Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that allegedly contained the falsified, fabricated, or plagiarized material.

(h) Any scientific or forensic analyses conducted.

(i) If not already provided to ORI, the institutional policies and procedures under which the investigation was conducted.

(j) Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.

(k) A statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct.

(1) If the investigation committee recommends a finding of research misconduct for an allegation, the investigation report must, for that allegation:

(i) Identify the individual(s) who committed the research misconduct.

(ii) Indicate whether the research misconduct was falsification, fabrication, and/or plagiarism.

(iii) Indicate whether the research misconduct was committed intentionally, knowingly, or recklessly.

(iv) State whether the other requirements for a finding of research misconduct, as described in § 93.103, have been met.

(v) Summarize the facts and the analysis which support the conclusion and consider the merits of any explanation by the respondent.

(vi) Identify the specific PHS support.

(vii) Identify whether any publications need correction or retraction.

(2) If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report must provide a detailed rationale.

(3) List of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.

§ 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.