



GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Confidentiality

U.S. Department of Health and Human Services

Office of the Assistant Secretary for Health

Office of Research Integrity (ORI)

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Public Health Service Policies on Research Misconduct
42 CFR Part 93 Guidance on Confidentiality
Contains Nonbinding Recommendations

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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 confidentiality 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 guidance document clarifies the obligations and limitations imposed on institutions by the updated regulation related to protecting the identities of respondents, complainants, witnesses, and other sensitive information during research misconduct proceedings.

There have been a few notable changes to the confidentiality provision in the updated regulation.¹ Overall, the updated regulation balances the need for confidentiality in research misconduct proceedings while providing institutions with the discretion to share information with appropriate parties based on a “need to know.” 42 CFR Part 93 specifies that disclosure of the identity of certain individuals while conducting research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law.² The updated regulation provides that institutions decide who has a “need to know,” and includes examples of individuals or entities that may have a need to know such as institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions.³ The updated regulation also includes witnesses among those whose identity should be protected from disclosure.⁴ In addition, the updated regulation provides that its limitations on disclosure of the identity of respondents, complainants, and witnesses no longer apply once the institution has made a final determination of research misconduct findings.

42 CFR Part 93 clarifies that institutions are not prohibited from managing published data or acknowledging that the data may be unreliable during or after the conclusion of a research misconduct proceeding. Institutions may take appropriate steps to correct the research record, including, for example, corrections to the published literature and reporting to funding agencies.⁵ Institutions have the discretion to manage published data or acknowledge that data may be unreliable while research misconduct proceedings are still underway, facilitating expeditious corrections or retractions of publications containing unreliable data. Further, institutions may take steps to correct errors in the research record even if the research misconduct proceeding does not result in a finding that research misconduct occurred. For instance, an institution may determine that a published article contains erroneous data or an image attributable to honest error. There may also be situations where the institution cannot determine who falsified or fabricated data but determines research records need to be corrected and, for example, notifies a journal, collaborating institution, or funding agency. Lastly, institutions must take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and committee members and to protect these individuals from retaliation by respondents and/or other institutional members.⁶

¹ 42 CFR § 93.106.

² § 93.106(a).

³ *Ibid.*

⁴ *Ibid.*

⁵ § 93.106(c).

⁶ § 93.300(d).

Key Elements of Confidentiality

Limited Disclosure

42 CFR Part 93 states that disclosure of the identities of respondents, complainants, and witnesses while conducting research misconduct proceedings is limited, to the extent possible, to those who need to know. Those who need to know may include institutional review boards, journal editors, publishers, co-authors, and collaborating institutions. This limitation on disclosure helps protect the reputation of those involved while research misconduct proceedings are underway. There may, however, be a need to inform certain individuals or entities to safeguard other interests, such as correcting the scientific literature or protecting human research participants. The “need to know” determination is made by the institution conducting the proceedings, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. RIOs are encouraged to consult with their institutional counsel to identify legal obligations that may impact disclosure during research misconduct proceedings. The regulatory limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once an institution has made a final determination of research misconduct findings.

Secure Handling of Records

42 CFR Part 93 requires that all research records and other evidence related to research misconduct proceedings must be sequestered in a secure manner.⁷ Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified.⁸ Disclosure is limited to those who need to know to carry out a research misconduct proceeding. Institutions are encouraged to coordinate with their compliance units, such as institutional review boards and institutional animal care and use committees, to ensure compliance with any other relevant laws, regulations, agreements, and ethical guidelines.

Sources of other relevant obligations to securely handle records may include, but are not limited to, Health and Human Services regulations for the protection of human subjects in research at 45 CFR Part 46, the [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#) and implementing regulations, import/export and biosafety regulations, and intellectual property or data sharing agreements. Institutions are encouraged to consult with institutional counsel to determine appropriate management of sequestered records.

Reporting to ORI

Institutions must disclose to ORI the identity of respondents, complainants, and other relevant persons in connection with an ORI review of research misconduct proceedings.⁹ Accordingly, although redactions

⁷ § 93.305(a). See also Guidance on Sequestration at <https://ori.hhs.gov/guidance-documents>.

⁸ § 93.106(b).

⁹ § 93.106(a).

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may be used to protect the identity of complainants or witnesses during the institutional proceedings, institutions must provide unredacted documents when the institutional record is transmitted to ORI.

ORI may notify and consult with other entities, including government funding agencies, institutions, journals, publishers, and editors, at any time if those entities have a need to know about or have information relevant to a research misconduct proceeding.¹⁰ In research misconduct proceedings involving more than one agency, HHS may refer to the other agency's (or agencies') evidence or reports if HHS determines that the evidence or reports will assist in resolving HHS issues. In appropriate cases, HHS may seek to resolve allegations jointly with the other agency or agencies.¹¹

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

¹⁰ § 93.401(a).

¹¹ § 93.107(b).

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.106 Confidentiality.

(a) Disclosure of the identity of respondents, complainants, and witnesses while conducting the research misconduct proceedings is limited, to the extent possible, to those who need to know, as determined by the institution, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. This limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once an institution has made a final determination of research misconduct findings. The institution, however, must disclose the identity of respondents, complainants, or other relevant persons to ORI pursuant to an ORI review of research misconduct proceedings under this part.

(b) Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who need to know to carry out a research misconduct proceeding.

(c) This section does not prohibit institutions from managing published data or acknowledging that data may be unreliable.

§ 93.107 Coordination with other agencies.

(a) When more than one agency of the Federal Government has jurisdiction over a research misconduct allegation, HHS will cooperate with the other agencies in designating a lead agency to coordinate the response of the agencies to the allegation. Where HHS is not the lead agency, it may, in consultation with the lead agency, take appropriate action.

(b) In research misconduct proceedings involving more than one agency, HHS may refer to the other agency's (or agencies') evidence or reports if HHS determines that the evidence or reports will assist in resolving HHS issues. In appropriate cases, HHS may seek to resolve allegations jointly with the other agency or agencies.

§ 93.300 General responsibilities for compliance.

Institutions must:

(a) Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part;

(b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective, and fair manner, including taking precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses;

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(c) Foster a research environment that promotes research integrity and the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;

(d) Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and committee members and to protect these individuals from retaliation by respondents and/or other institutional members;

(e) Provide confidentiality consistent with § 93.106 to all respondents, complainants, and witnesses in a research misconduct proceeding, and to research subjects identifiable from research records or other evidence;

(f) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and other evidence;

(g) Cooperate with HHS during any research misconduct proceeding or compliance review, including addressing deficiencies or additional allegations in the institutional record if directed by ORI;

(h) Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and

(i) Have an active research integrity assurance.

§ 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.

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(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.

§ 93.401 Interaction with other entities and interim actions.

(a) ORI may notify and consult with other entities, including government funding agencies, institutions, journals, publishers, and editors, at any time if those entities have a need to know about or have information relevant to a research misconduct proceeding.

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(b) If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice (DOJ), the HHS Office of Inspector General (OIG), or other appropriate investigative body.

(c) ORI may provide expertise and assistance to the DOJ, OIG, PHS offices, other Federal offices, and state or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.

(d) ORI may notify affected PHS offices and funding components at any time to enable them to take appropriate interim actions.

(e) The information provided will not be disclosed as part of the peer review and advisory committee review processes but may be used by the Secretary in making decisions about the award or continuation of funding.

(f) ORI may refer a research misconduct matter to the [Suspension and Debarment Official] SDO at any time for consideration under the HHS suspension and debarment regulations. ORI may provide technical assistance and share other information that the SDO needs to know to consider the referred matter.