



GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Respondents

U.S. Department of Health and Human Services

Office of the Assistant Secretary for Health

Office of Research Integrity (ORI)

2026

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

Table of Contents

Overview	3
Institutional Responsibilities to Respondents	3
Adding Respondents to a Proceeding	4
Unresponsive or Uncooperative Respondents	5
Protecting and Restoring the Reputations of Individuals Named in Allegations.....	5
Pertinent Sections of 42 CFR Part 93 (2024)	7
§ 93.105 Evidentiary standards.	7
§ 93.106 Confidentiality.	7
§ 93.300 General responsibilities for compliance.	8
§ 93.304 Institutional policies and procedures.	8
§ 93.305 General conduct of research misconduct proceedings.....	9
§ 93.307 Institutional inquiry.	10
§ 93.308 Notice of the results of the inquiry.	12
§ 93.310 Institutional investigation.....	12
§ 93.312 Opportunity to comment on the draft investigation report.	13

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 respondents 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.

Date of Issuance: May 2026

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](#)). Every research misconduct case is unique, and some cases involve more than one respondent. The updated regulation addresses proceedings that involve multiple respondents. This document provides guidance for institutions about respondents, including multiple respondents as outlined in the updated regulation.¹ Additionally, this document suggests best practices when dealing with unresponsive or uncooperative respondents, which can occur either where the research misconduct allegedly occurred or when a respondent leaves an institution. This document also discusses restoring the reputations of respondents against whom no finding of research misconduct is made.

Institutional Responsibilities to Respondents

Before misconduct proceedings are fully underway, ORI recommends that the Research Integrity Officer (RIO), inquiry committee, and/or investigation committee consider how, in practical terms, they will fulfill their regulatory responsibilities to each respondent. Institutional responsibilities include:

- Notifying each respondent in writing of the allegations against them, including additional allegations raised during the proceeding.²
- Limiting disclosure of each respondent's identity as described in 42 CFR § 93.106(a).³
- 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 each respondent.⁴ ORI recommends affording each respondent the opportunity to present documentation of a conflict of interest with a proposed committee member if one exists.
- Giving each respondent copies of, or supervised access to, the sequestered research records where appropriate.⁵
- Notifying each respondent whether the relevant inquiry found that an investigation is warranted and providing a copy of the inquiry report, a copy of or reference to 42 CFR Part 93, and the institution's policies and procedures adopted under its research integrity assurance.⁶

¹ 42 CFR §§ 93.305(d) and 93.310(h).

² §§ 93.307(c), 93.310(c), and 93.310(j).

³ § 93.300(e). 42 CFR § 93.106 explains, "Disclosure of the identity of respondents . . . 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. . . . This limitation on disclosure of the identity of respondents . . . no longer applies once an institution has made a final determination of research misconduct findings. The institution, however, must disclose the identity of respondents . . . to ORI pursuant to an ORI review of research misconduct proceedings under this part." See also guidance on Confidentiality <https://ori.hhs.gov/guidance-documents>.

⁴ § 93.300(b).

⁵ § 93.305(b).

⁶ § 93.308(a).

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

- Providing each respondent an opportunity to review and comment on the inquiry report.⁷
- Providing each respondent transcripts of witness interviews conducted during the investigation.⁸
- Giving each respondent a copy of the draft investigation report and, concurrently, a copy of or supervised access to the research records and other evidence that the investigation committee considered or relied on.⁹
- Providing each respondent an opportunity to submit comments on the draft investigation report to the institution within 30 days of receipt.¹⁰
- Giving due consideration to credible evidence of honest error or difference of opinion presented by each respondent.¹¹
- Making all reasonable, practical efforts, if requested and as appropriate, to protect or restore the reputation of each respondent against whom no finding of research misconduct is made.¹²

Adding Respondents to a Proceeding

During the investigation stage, institutions must consider the prospect of additional researchers being responsible for the alleged research misconduct.¹³ At any stage of a research misconduct proceeding, an institution may identify additional respondent(s) based on available evidence and add the new respondent(s) to the ongoing research misconduct proceeding.

If an institution identifies additional respondents during an inquiry or investigation, the institution may, but is not required to, conduct a separate inquiry for each new respondent. Each additional respondent identified during an inquiry or investigation must be notified of the allegation(s) and provided an opportunity to respond consistent with 42 CFR Part 93.¹⁴

Institutions may include multiple respondents on a single inquiry report.¹⁵ A separate investigation report is required for each respondent.¹⁶

⁷ § 93.307(g)(3).

⁸ § 93.310(g). See guidance on Interviews at <https://ori.hhs.gov/guidance-documents>.

⁹ § 93.312(a).

¹⁰ § 93.312(a).

¹¹ § 93.105(b)(2).

¹² § 93.304(c).

¹³ § 93.310(h).

¹⁴ § 93.305(d).

¹⁵ Each regulatory stage of a research misconduct proceeding (assessment, inquiry, and investigation) has a separate function. An assessment's purpose is to determine whether an allegation warrants an inquiry; an inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation; and an investigation reaches a decision on the merits of the allegation(s). Considerations involving each respondent may emerge at any phase in the proceedings, including potential research misconduct activity at multiple institutions. See Assessments Guidance and Multiple Institutions Guidance for more information here: <https://ori.hhs.gov/guidance-documents>

¹⁶ § 93.310(c)(3).

Unresponsive or Uncooperative Respondents

During research misconduct proceedings, respondents occasionally fail to respond to institutional requests for contact or information related to the proceedings for a variety of reasons. These reasons can include, for example, a move to a new institution (particularly outside the country where the alleged misconduct occurred), attempted avoidance of potential findings of research misconduct or administrative actions, health concerns, or other personal issues. Regardless of the reason, institutions may face difficulty completing research misconduct proceedings when a respondent does not respond to requests for documentation, interviews, or other information relevant to the allegations.

To move research misconduct proceedings forward, when a respondent is unresponsive or uncooperative, institutions may consider a range of actions, including:

- Documenting attempts to contact the respondent and the respondent's failure to respond or cooperate.
- Using alternative means to obtain and sequester evidence, such as IT forensic support for capturing data and email communications on available servers.
- Interviewing witnesses with knowledge relevant to the respondent's potential role in the alleged research misconduct.
- Offering further channels for the respondent to communicate with the institution.
- Identifying all institutional policies that may relate to the respondent's failure to respond or cooperate.
- Issuing findings based on available evidence, regardless of the respondent's failure to respond.

If otherwise consistent with institutional policy and 42 CFR Part 93, institutions may complete a research misconduct proceeding in which the respondent has not responded, cooperated, or otherwise participated in the proceeding.

Protecting and Restoring the Reputations of Individuals Named in Allegations

42 CFR Part 93 states that institutional policies and procedures must provide for all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.¹⁷ Institutions have discretion in this area, and ORI provides the following best practices for institutions:

- Consult with respondents as to their preferences following the proceeding. Some respondents may wish for the institution to inform individuals who were made aware of the proceeding on a "need to know" basis or via other means of the outcome of the proceeding. Others may wish for the institution to send a broadly disseminated message to members of the relevant research

¹⁷ § 93.304(c).

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

community. Still others may wish for the institution not to disclose the outcome of the proceeding.

- A determination of what is “reasonable and practical” lies with the institution on a case-by-case basis.
- 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.
- Consider any aggravating or mitigating circumstances when determining a fair approach in restoring the reputations of respondents, witnesses, and others involved in research misconduct proceedings.

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

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.105 Evidentiary standards.

(a) *Standard of proof.* An institutional or HHS finding of research misconduct must be proved by a preponderance of the evidence.

(b) *Burden of proof.*

(1) The institution or HHS has the burden of proof for making a finding of research misconduct. A respondent's destruction of research records documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.

(2) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

(3) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, any mitigating factors relevant to a decision to impose administrative actions after a research misconduct proceeding.

§ 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.

§ 93.300 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;

(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.

§ 93.304 Institutional policies and procedures.

Institutions seeking an approved research integrity assurance must have written policies and procedures for addressing allegations of research misconduct. Such policies and procedures must:

(a) Address and be consistent with all applicable requirements pertaining to institutional responsibilities included in this part;

(b) Include and be consistent with applicable definitions in this part; and

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

(c) Provide for all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

§ 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.

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

(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.

§ 93.307 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—*

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

(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.

§ 93.308 Notice of the results of the inquiry.

(a) *Notice to respondent.* The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its research integrity assurance.

(b) *Notice to complainant.* The institution is not required to notify a complainant whether the inquiry found that an investigation is warranted. The institution may, but is not required to, provide relevant portions of the report to a complainant for comment. If an institution provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.

§ 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

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

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.

§ 93.312 Opportunity to comment on the draft investigation report.

(a) The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied on. The respondent must submit any comments on the draft report to the institution within 30 days of receiving the draft investigation report.

(b) The institution may provide the complainant a copy of the draft investigation report or relevant portions of that report. The comments of the complainant, if any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.