GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Interviews

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
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Table of Contents

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 interviews 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 both the requirements and practical considerations for conducting, recording, and transcribing interviews under the updated regulation.

42 CFR Part 93 notes that during the inquiry phase of research misconduct proceedings, the institution may interview witnesses or respondents who could provide additional information for the institution's review.[1] The regulation does not require that interviews conducted during the inquiry phase are recorded and transcribed. During the investigation phase, however, 42 CFR Part 93 specifies that institutions must conduct, record, and transcribe interviews of 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.[2]

Although the updated regulation does not require the institution to conduct, record, or transcribe interviews prior to the investigation, doing so can help the institution maintain an accurate record of the proceedings and may be useful during subsequent stages of the proceeding. If the institution considers or relies on a pre-investigation interview recording and/or transcription, these become part of the institutional record.[3]

What Constitutes an Interview

42 CFR Part 93 requires institutions to record and transcribe interviews during the investigation phase, but institutions have discretion to determine whether a particular interaction constitutes an interview. In making such determinations, institutions may consider factors such as:

- **Subject matter of the interaction.** When the subject matter of the interaction has potential evidentiary value for a research misconduct proceeding, this factor makes it more likely that the conversation should be considered a formal interview. When the subject matter of the interaction addresses general procedural or scheduling matters unlikely to have evidentiary value, such as a potential complainant asking the Research Integrity Officer (RIO) about the process involved in making an allegation, this factor makes it more likely that the conversation should not be considered a formal interview.
- **How the interaction arises.** If an institution requests the interaction, this factor makes it more likely that the conversation should be considered a formal interview.
- **Formality of the interaction.** When the interaction takes place under circumstances or a setting that indicates greater formality, such as a planned gathering in a conference room, this factor makes it more likely that the conversation should be considered a formal interview.

[1] 42 CFR § 93.307(e)(3).
[2] § 93.310(g).
[3] § 93.220(a)(2).

- **Nature of the interaction.** When the interaction involves an institution engaging in dialogue, rather than only conducting an intake of information, this factor makes it more likely that the conversation should be considered a formal interview.
- **Questions prepared in advance.** When an institution prepares questions in advance, this factor makes it more likely that the conversation should be considered a formal interview.

Institutions are not required to consider these factors when they determine if an interaction constitutes an interview; there may be additional or different factors and institutions can approach each interaction on a case-by-case basis.

Institutions should confer with counsel about any local laws and policies that may affect the recording or documentation of their interactions relating to research misconduct proceedings, regardless of whether institutions determine the interactions constitute interviews.

Interview Requirements

Interview requirements differ depending on the stage of the research misconduct proceeding. At the assessment stage, the respondent should not be notified or interviewed.[4] The RIO may conduct an interview with the complainant, but that interview is not required to be recorded or transcribed.

At the inquiry stage, the institution may interview the respondent or witnesses that would provide additional information for the institution's review, but these interviews are not required to be recorded or transcribed.[5]

At the investigation phase, the institution must record and transcribe interviews.[6] The regulation specifies that, as part of the investigation, institutions 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.[7] The regulation also requires the following for interviews at the investigation stage:

- Any exhibits shown to the interviewee must be numbered and referred to by that number during the interview.
- The interview transcript must be made available to the relevant interviewee for review and correction.
- The transcript(s) with any corrections and numbered exhibits must be included in the institutional record.
- The respondent must not be present during witness interviews.

[4] *See* ORI's Assessments Guidance at https://ori.hhs.gov/guidance-documents
[5] § 93.307(e)(3).
[6] § 93.310(g)(1).
[7] § 93.310(g).

- The respondent must be provided with the transcripts, which may be redacted by the institution to protect the identity of the interviewee (see below).[8]

42 CFR Part 93 requires that institutions take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and committee members and protect these individuals from retaliation by respondents and/or other institutional members.[9] The regulations permit institutions to use redactions to protect the identity of the interviewee. 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 42 CFR Part 93. Interviewees should be advised of this requirement and its potential implications.

The purpose of giving interviewees an opportunity to review the transcript is to suggest corrections to the transcription itself (e.g., to correct a transcription-related error or correct a technical term that was inaudible). Interviewees should not make content-related changes. They should not add, change, or delete a statement. ORI recommends institutions append a copy of the interviewee's requests for correction to the transcript for inclusion in the investigation report. As recorded and transcribed interviews provide evidence that may be used to determine whether research misconduct occurred, attention to accuracy is vital.

Practical Considerations Involving Interviews

Various factors may affect an institution's decision whether to record and transcribe pre-investigation interviews. Interviewees may hesitate to speak openly if their interview is being recorded.[10] On the other hand, they may share information that is critical to the institutional process of handling the allegations and determining whether research misconduct occurred. Recorded and transcribed interviews may become an important part of the pre-investigation record upon which the institution relies later in the proceeding.

If pre-investigation interviews are not recorded and transcribed, the interviewer(s) should consider documenting them for the institutional record. For example, ORI recommends RIOs take notes during or shortly after such interviews and include their notes in the institutional record. RIOs may consider sending these notes to the interviewee to confirm accuracy. If an institution opts to record and transcribe interview(s) during the inquiry, the transcript(s) must be included in the inquiry report.[11]

Interviewers may wish to consult with their institutional counsel as they prepare to conduct interviews. Legal advice may be particularly helpful in framing questions properly in the context of the regulatory criteria for making a determination of whether research misconduct occurred.[12] Institutions may also

[8] § 93.310(g)(2)-(5).
[9] § 93.300(d).
[10] If a proposed interviewee declines to participate in an interview, ORI suggests institutions include documentation of the interview request and the proposed interviewee's response in the institutional record.
[11] § 93.309(a)(6). When an interview is recorded but not transcribed, the recording becomes part of the institutional record under § 93.220 and is subject to the maintenance and custody requirements at § 93.318.
[12] § 93.103.

find it helpful to assign questions or topics to specific committee members beforehand, while carefully considering the sequence of questions as well as the sequence of interviews as part of the information gathering process. Sometimes it can be advisable to interview the complainant(s) first, and then witnesses, and, finally, the respondent(s). Establishing an appropriate sequence of interviews can strengthen the institution's ability to acquire relevant facts as the proceedings progress, avoid the need for second interviews with individuals, and assess credibility of witnesses, including the complainant(s) and respondent(s).

For uniformity and fairness, institutions may wish to draft and read a standard introduction that explains the purpose of the interview, the role of those present, and the rights and responsibilities of the interviewee in keeping with institutional policy and applicable regulations.

Although committee members posing interview questions should be advised not to interrupt the interviewee, there may be times when the interviewee needs to be redirected back to the topic at hand, particularly when the interviewee's testimony is lengthy and not relevant to the allegations or questions posed. Committee members should also be discouraged from asking leading or accusatory questions of the interviewee. Respect for the dignity of the individual and the objectivity of the process represent key factors in setting the tone for interviews and the overall proceeding.

Interview transcripts often constitute evidence that the institution heavily relies on to make research misconduct determinations. They also are an important component of what ORI considers when conducting its regulatory oversight review of the institution's research misconduct proceedings. 42 CFR Part 93 specifies that, during any interview conducted as part of the institutional investigation, all exhibits shown to an interviewee must be numbered and referred to by that number during the interview (e.g., "Exhibit #001").[13] ORI recommends institutions create a single numbered list of exhibits for the entire research misconduct proceeding, and use the same exhibit numbers across interviews. For the clarity of the transcript, it is useful to describe the exhibit or relevant part of the exhibit, such as image depicted, figure number, journal or document title, page number, and date of publication or creation, if applicable. This practice enables those reading the transcript to associate exhibits with verbal testimony and help ensure the accuracy of statements made in the interview. It is also advisable to have all participants verbally identify themselves at the beginning of the interview to ensure accuracy of the transcript. The institution also may consider preparing a list of relevant vocabulary, such as technical terms related to the topics discussed in the interview, to aid the transcription of the interview. This list may be particularly useful if the institution uses a transcription service or software program to transcribe recordings, instead of a person performing real-time transcription. Additionally, it may be advisable to have a translator available to assist non-native English speakers.

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 interviews, please reach out to ORI at any time for guidance by calling (240) 453-8400 or emailing AskORI@hhs.gov.

[13] § 93.310(g)(2).

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.103 Requirements for findings of research misconduct.

A finding of research misconduct made under this part requires that:

(a) There be a significant departure from accepted practices of the relevant research community; and

(b) The misconduct be committed intentionally, knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of the evidence.

§ 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.

§ 93.300 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.

§ 93.307 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* —

(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.

§ 93.309 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.

§ 93.310 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.

§ 93.318 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.