GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Pursuing Leads

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
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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 pursuing leads 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 requires that institutions conducting research misconduct investigations must pursue leads. Specifically, institutions must "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."[1]

The Importance of Pursuing Leads During the Investigation Phase

If an institution does not diligently pursue all leads and significant issues during an investigation, it could have a negative impact on the efficiency and outcome of misconduct proceedings—including the timely sequestration of potential evidence. Undiscovered research misconduct may also lead to unreliable data remaining in the literature, which generally harms the scientific enterprise.

By pursuing all significant issues and leads, the institution may:

- Improve the thoroughness, competence, objectivity, and fairness of research misconduct proceedings.
- Avoid the risk of having an insufficient investigation.
- Uncover evidence of which individual(s) committed research misconduct and whether it was committed intentionally, knowingly, or recklessly.
- Determine appropriate institutional actions and their implementation.

Responding to Research Misconduct Allegations

Institutions must respond to each research misconduct allegation in a thorough, competent, objective, and fair manner.[2] When pursuing leads during the investigation stage, institutions should consider potential evidence in research records, including grant applications and published papers. This analysis may indicate the possibility of more widespread research misconduct.

Examples of leads that may indicate a need to expand the investigation beyond the initial allegation(s) include the following:

[1] 42 CFR § 93.310(j).
[2] § 93.300(b).

- Patterns of behavior, such as the occurrence of falsifications or fabrications in multiple figures in the same paper or in multiple papers and/or grant applications over an extended period of time.[3]
- Occurrence of the same type of fabrication or falsification in several figures, such as:
    - Reuse and relabeling of western blot panels, microscopy images, or flow cytometry graphs; or other inappropriate reuse of the same source data.
    - Reuse of a portion or section of a western blot panel, microscopy image, or other source data.
    - Reuse and relabeling with manipulation or alteration of the image or data.
- Repeated or extensive use of methodology or technique that a respondent used or published to generate the questioned data.
- Testimony or other evidence that experiments were not performed, such as:
    - Respondent rarely present in the laboratory or not utilizing the laboratory instruments necessary to conduct the experiments and generate the data.
    - No laboratory notebooks or research records produced.
    - A paucity of original data on laboratory computers, hard drives, flash drives, or other experimental hard drives (e.g., source data spreadsheets for RT-PCR, ELISA, FACS, microscopy).

In evaluating whether there may be additional instances of possible research misconduct relevant to the investigation, it is important to examine a respondent's papers and grant applications that could include figures or other data elements which are similar to those in the initial allegation(s). It is useful to look for patterns of behavior, such as the reuse or repurposing of research materials in published figures and grant applications, and to identify the individuals who performed relevant experiments or generated questioned images.

While pursuing leads is only required during a research misconduct investigation,[4] institutions are encouraged to remain alert for indications of significant issues or additional leads during all stages of the proceeding. It is possible the extent of research misconduct is limited to the initial allegation(s). It is also possible the extent of research misconduct can be discovered only by expanding on the leads identified during the research misconduct proceeding.

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

[3] In cases involving papers or grant applications over multiple years, it is important to consider the applicability of the subsequent use exception in 42 CFR § 93.104(b)(1). *See* ORI guidance on Subsequent Use Exception at https://ori.hhs.gov/guidance-documents.
[4] § 93.310(j)

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.104 Time limitations.

(a) *Six-year limitation.* This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.

(b) *Exceptions to the six-year limitation.* Paragraph (a) of this section does not apply in the following instances:

(1) *Subsequent use exception*. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the use of, republication of, or citation to the portion(s) of the research record (e.g., processed data, journal articles, funding proposals, data repositories) alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent.

(i) When the respondent uses, republishes, or cites to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the allegations were received by HHS or an institution, this exception applies.

(ii) For research misconduct that appears subject to the subsequent use exception, institutions must document their determination that the subsequent use exception does not apply. Such documentation must be retained in accordance with § 93.318.

(2) *Exception for the health or safety of the public.* If ORI or the institution, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public, this exception applies.

§ 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.

§ 93.310 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.