GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Multiple Institutions

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Research Integrity (ORI)
2025

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 multiple institutions 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: December 2025

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). When research misconduct allegations emerge in the context of research conducted across multiple institutions, the proceedings to respond to those allegations can be complex and challenging. 42 CFR Part 93 includes new language for research misconduct proceedings involving multiple institutions. The regulation requires that when institutions decide to conduct a joint research misconduct proceeding, they must designate a lead institution.[1] Issues may arise that are not anticipated at the outset of research misconduct proceedings involving multiple institutions. This guidance document includes considerations related to joint proceedings that are not addressed specifically by the regulation.

Conducting Proceedings Jointly

Before deciding to conduct a joint research misconduct proceeding, institutions should confirm that their institutional policy allows for the conduct of joint proceedings and develop a clearly documented understanding, for example in a Memorandum of Understanding (MOU) or other written agreement, that articulates how the joint misconduct proceeding will be conducted in accordance with 42 CFR Part 93. A written agreement that details obligations of the participating institutions can help clarify roles and responsibilities and promote well-functioning proceedings. Institutions are encouraged to consult their legal counsel regarding the form and content of such agreements.

As previously noted, the regulation requires that one institution must be designated as the lead institution if a joint research misconduct proceeding is conducted. In addition to stating which institution has been designated as the lead, an MOU or other agreement might specify the roles and responsibilities of each institution including, but not limited to, the following:

- The roles of each institution in obtaining and securing research records and other evidence pertinent to the proceeding, including witness testimony.
- How other institutions will cooperate with and assist the lead institution.
- How the institutions will determine the applicable research misconduct policies and procedures.
- Points of contact at each institution for communication between institutions and to communicate with ORI.
- How to protect confidentiality consistent with 42 CFR § 93.106, including identifying those persons at the respective institutions with a need to know.
- Whether the inquiry and/or investigation committee members will be from the lead institution only or from multiple institutions.
- How interviews will be conducted.
- The schedule of committee meetings to facilitate thorough, timely, and fair proceedings.
- Whether the lead institution or the institutions jointly will make the determination to proceed to inquiry or investigation.

[1] 42 CFR § 93.305(e).

- Whether the lead institution or the institutions jointly will determine whether research misconduct occurred.
- How the institutions will determine what institutional actions should be taken.
- How a disagreement or conflict among institutions will be addressed.

Designating a Lead Institution

Institutions have discretion to choose their approach to designating a lead institution. For example, they might designate the institution where the respondent is currently employed as the lead institution. Or the lead institution may be where the majority of the relevant research materials are located. Sometimes these two intersect, particularly where a researcher's program is transferred to another institution. The approach of designating the lead institution where the respondent is currently employed may be appropriate, even if one or more allegations involve research at the respondent's prior institution, since research materials may or may not be transferred by respondents between institutions. Another approach might be to evaluate which institution has the largest share of oversight responsibility for the alleged research misconduct. For example, the institution with the largest number of allegations to which 42 CFR Part 93 applies may be designated as the lead institution. Institutions may contact ORI for technical assistance.

Conducting Proceedings Separately

At any time, an institution may prefer to conduct research misconduct proceedings independently. In addition, some institutions may have policies or procedures that prohibit or prevent them from participating in joint proceedings. If an institution decides to address allegations involving multiple institutions on its own, it is important for the Research Integrity Officer (RIO) to communicate to the inquiry and investigation committee members that their review and findings should focus only on the allegations involving PHS-funded research at their own institution. Unless there is a joint proceeding under which a lead institution is designated, institutions should only review and make research misconduct determinations on allegations involving PHS funds at their own institution.

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 multiple institutions, 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)

§ 93.305 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.