GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Conflicts of Interest

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Research Integrity (ORI)
2026

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 conflicts of interest 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: September 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). Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under 42 CFR Part 93.[1] In practice, this includes the requirement that institutions take precautions to ensure that all such officials and members honestly and impartially carry out their duties and do not have unresolved personal, professional, or financial conflicts of interest (COIs) with those involved in the research misconduct proceeding.

COI concerns may arise for any institutional members involved in research misconduct proceedings, including but not limited to Research Integrity Officers (RIOs), committee members, subject matter experts (SMEs), and Institutional Deciding Officials (IDOs), regardless of the size of the institution. Institutions are responsible for ensuring that all institutional members involved in research misconduct proceedings do not have unresolved COIs with the complainant, respondent, or witnesses.[2] Accordingly, resolving COIs is essential for an institution to address allegations of research misconduct in a thorough, competent, objective, and fair manner.

This guidance is limited to COIs under 42 CFR Part 93. ORI encourages institutions to work with their counsel if an actual or apparent COI emerges at any time during research misconduct proceedings and to document COI issues as part of the institutional record.

Examples of Conflicts of Interest

42 CFR Part 93 states that institutions have general responsibilities for complying with this regulation, including that institutions ensure any individuals responsible for carrying out any part of research misconduct proceeding do not have an unresolved personal, professional, or financial COI with the complainant, respondent, or witnesses.[3] In practical terms, this means that any institutional official who is involved in addressing research misconduct allegations may not have an unresolved COI.[4]

The updated regulation does not define a COI, but rather, identifies three types of COIs that must be addressed by institutions and committee members during a research misconduct proceeding: personal, professional, and financial.[5] Examples of COIs that institutions may encounter in research misconduct proceedings include:

- Personal
    - Having a close friendship, romantic relationship, or a history of personal animosity with the complainant, respondent, or a witness

[1] 42 CFR § 93.214(b).
[2] § 93.300(b).
[3] § 93.300(b).
[4] § 93.219.
[5] § 93.214(b).

    - Being a family member or relative of any person involved in the proceeding
    - Serving currently or formerly as a personal mentor and/or close academic advisor of the respondent or complainant
- Professional
    - Being a direct collaborator or coauthor on one or more publications with the respondent or complainant
    - Serving as the direct supervisor, department chair, or subordinate of the respondent or complainant
    - Competing directly with the respondent for the same federal funding or having an academic rivalry with the respondent or complainant
    - Serving as coprincipal investigators (co-PIs) on an active grant or sharing substantial laboratory resources with the respondent or complainant
- Financial
    - Holding shares, equity, or patent rights in a company whose product, valuation, or market share is directly affected by the research in question
    - Serving as a paid consultant, board member, or employee of an entity linked to the disputed research
    - Having direct responsibility over an investment or contract that could lose funding if a finding of misconduct is made
    - Standing to gain or lose personal income depending on the outcome of the proceeding

42 CFR Part 93 distinguishes between apparent and actual COIs in multiple sections.[6] The list above does not include every situation that may give rise to an actual or apparent COI. An apparent COI exists when a reasonable person would perceive that an individual's personal, professional, or financial interests could improperly influence their actions, even if no such COI actually exists. Just as institutions have a responsibility to resolve actual COIs, they must also address apparent COIs in a manner that is consistent with the regulation and their institutional policy.

Small Institutions

42 CFR Part 93 defines a small institution as an institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by this part without actual or apparent COIs.[7] These institutions may establish an assurance with ORI by filing the Small Institution Statement in lieu of a formal institutional policy.[8] By submitting the Small Institution Statement the institution agrees to report all allegations of research misconduct to ORI.

ORI or another appropriate HHS entity will work with the institution to advise on a regulation-compliant process for handling allegations that are appropriate for its institutional setting. If a small institution has

[6] §§ 93.240, 93.305(f)(1), and 93.502.
[7] § 93.240.
[8] *See* guidance on Small Institutions at https://ori.hhs.gov/guidance-documents.

or believes that it has a COI during any phase of a research misconduct proceeding, it may contact ORI for guidance.

An institution must address any potential, perceived, or actual personal, professional, or financial COIs between members of the committee or consortium, or other person, and the complainant, respondent, or witnesses. If a COI cannot be resolved due to limited human resources or infrastructure, a small institution may consider using a committee, consortium, or person acting on its behalf to conduct research misconduct proceedings.

Committee Members and Subject Matter Experts

During the course of research misconduct proceedings, an institution may convene a committee to address research misconduct allegations at the inquiry stage and must do so at the investigation stage. When assembling a committee, an institution must address any potential, perceived, or actual personal, professional, or financial COIs between members of the committee, consortium, or other person acting on behalf of the institution and the complainant, respondent, or witnesses, both at the time of convening a committee and at any time during the course of the proceedings possible COI issues arise.[9]

To ensure procedural fairness, it may be advisable to afford respondents the opportunity to raise and address any COI concerns as to persons involved in the proceedings. In convening committees, institutions may also provide the respondent with the names of proposed members as a precaution, allowing the respondent to demonstrate that one or more members' COI would hinder their objectivity. In such cases where the COI concern is deemed valid, the institution may choose to identify another member to serve on the committee.

In resolving any actual or apparent COIs, institutions may take several steps. These may include declining to invite an individual to serve on a committee, documenting any apparent COI and management of such apparent COI if possible, or, if a conflict arises after the committee is convened, recusal of the affected individual. These steps and their documentation as part of the institutional record help ensure that proceedings are conducted in a thorough, competent, objective, and fair manner.

An institution may have a policy or procedure in place for an institutional official to recuse themselves from research misconduct proceedings if there is an actual or apparent COI, affording the option to appoint an independent individual or group to address the proceedings.[10] In such cases, institutions should consult with their counsel to determine whether a COI issue is valid or will hinder the impartiality of the proceedings. It may be useful for institutions to have a standard appointment document for officials and committee members involved in research misconduct proceedings to address COI requirements.

Good faith as applied to an institutional or committee member includes cooperating with a research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an

[9] § 93.305(f)(1). *See also* guidance on Institutional Committees at https://ori.hhs.gov/guidance-documents.
[10] *See* § 93.305(f) (discussing use of a committee, consortium, or other person for research misconduct proceedings).

institution meet its responsibilities under 42 CFR Part 93.[11] An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial COIs with those involved in the research misconduct proceedings.

42 CFR Part 93 also clarifies that institutions may employ SMEs during research misconduct proceedings. These individuals are subject to the same institutional COI obligations as IDOs and other committee members to ensure fair proceedings. In all cases, institutions must take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of individuals with appropriate scientific expertise who do not have unresolved personal, professional, or financial COIs relevant to the proceedings.[12]

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

[11] § 93.214(b).
[12] § 93.310(f).

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.214 Good faith.

(a) Good faith as applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowledge of or reckless disregard for information that would negate the allegation or testimony.

(b) Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under this part. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

§ 93.219 Institutional member.

Institutional member or members means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, or attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.

§ 93.240 Small institution.

Small institution means an institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by this part without actual or apparent conflicts of interest.

§ 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.

§ 93.305 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.

§ 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.

§ 93.502 Appointment of the Administrative Law Judge.

(a) Within 30 days of receiving a notice of appeal, the DAB Chair, in consultation with the Chief ALJ, must designate an ALJ to determine whether the notice of appeal is timely filed and within the ALJ's jurisdiction under this subpart. If the appeal is determined to be timely and within the ALJ's jurisdiction, the ALJ shall decide the reasonableness of the ORI research misconduct findings and proposed HHS administrative actions in accordance with this subpart. The ALJ shall dismiss an appeal if it is untimely or not within the ALJ's jurisdiction under this subpart.

(b) No ALJ may serve in any proceeding under this subpart if they have any actual or apparent conflict of interest, bias, or prejudice that might reasonably impair their objectivity in the proceeding.

(c) Any party to the proceeding may request the ALJ to withdraw from the proceeding because of an actual or apparent conflict of interest, bias, or prejudice under paragraph (b) of this section. The motion to disqualify must be timely and state with particularity the grounds for disqualification. The ALJ may rule upon the motion or certify it to the Chief ALJ for decision. If the ALJ rules upon the motion, either party may appeal the decision to the Chief ALJ.

(d) An ALJ must withdraw from any proceeding for any reason found by the ALJ or Chief ALJ to be disqualifying.