GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

RIOs and Institutional Officials

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 institutional officials 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 defines several important roles involved in research misconduct proceedings, including the Institutional Deciding Official (IDO), the Research Integrity Officer (RIO), and the Institutional Certifying Official (ICO). This guidance document highlights the different responsibilities of each institutional role.

Research Integrity Officer

The RIO is the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93.[1] The RIO is typically the individual who responds to an allegation of research misconduct when it is received and promptly conducts an assessment, though another designated institutional official may perform those actions.[2] If the RIO or another designated institutional official determines that requirements for an inquiry are met, they must document the assessment, promptly sequester all research records and other evidence consistent with § 93.305(a), and promptly initiate the inquiry.[3] If a proceeding advances to an inquiry, the RIO (or another designated institutional official) may conduct an inquiry alone, utilizing one or more subject matter experts to assist them in the inquiry (if needed), or they may convene a committee to conduct the inquiry.[4] In contrast, the RIO (or another designated institutional official) cannot conduct an investigation alone, as institutions must use a committee for the investigation.[5]

In practice, the RIO may be responsible for numerous activities that are necessary during research misconduct proceedings on a case-by-case basis. These activities may include sequestering and analyzing evidence, interviewing respondents and witnesses, and reporting to institutional officials and committees.[6] RIOs should also regularly communicate with ORI about the progress of cases.

Institutional Deciding Official

The IDO is the institutional official who makes final determinations on allegations of research misconduct and any institutional actions.[7] The same individual cannot serve as the IDO and the RIO.[8] In general, the

[1] 42 CFR § 93.233.
[2] § 93.306.
[3] § 93.306(c)(2).
[4] §§ 93.307(e)(2) and 93.200. Institutions often rely on subject matter experts to evaluate the accepted practices relevant to an allegation of research misconduct at the time they took place per 42 CFR part 93, PHS funding components, and professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards. *See also* guidance on Institutional Committees at https://ori.hhs.gov/guidance-documents.
[5] § 93.310.
[6] *See* guidance on Institutional Committees https://ori.hhs.gov/guidance-documents.
[7] § 93.218.
[8] *Id.*

RIO's role is to facilitate the conduct of proceedings, while the IDO's role is to determine the outcome of the proceedings.

The IDO's final determination of research misconduct findings must be provided in a written decision that includes whether the institution found research misconduct; if so, who committed the misconduct; and a description of relevant institutional actions taken or to be taken.[9] The IDO's written decision must be transmitted to ORI with the institutional record at the conclusion of research misconduct proceedings within designated time limits.[10]

Institutional Certifying Official

The ICO is the institutional official responsible for assuring on behalf of an institution that the institution has written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93.[11] The ICO also assures that the institution complies with its own policies and procedures and the requirements of 42 CFR Part 93.[12] The ICO is also responsible for certifying the content of the institution's initial assurance to ORI and the institution's annual report, which contains information specified by ORI on the institution's compliance with 42 CFR Part 93, and ensuring the report is submitted to ORI, as required.[13]

The ICO is sometimes called the "Institutional Official," because ORI considers this individual as an institutional member that can make decisions on behalf of the institution and serves as the main contact for the institution's assurance. Institutions may permit the same individual to serve as both the ICO and the IDO. When an institution establishes an assurance with ORI via the Research Integrity Assurance Establishment form PHS-7091 or online in the Annual Report on Possible Research Misconduct (ARPRM) system, the ICO may designate a secondary official to act on their behalf in making decisions related to the institution's assurance.

Responsible Conduct of Research Coordinator (Optional)

Institutions that apply for or receive PHS funding for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, are required to foster a research environment that promotes research integrity and the responsible conduct of research, discourages research misconduct, and respond promptly to allegations of research misconduct.[14]

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[9] § 93.314. It is important for the IDO to keep in mind that, in accordance with § 93.103, a finding of research misconduct requires that (a) there be a significant departure from accepted practices of the relevant research community; (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence. *See also* guidance on State of Mind at https://ori.hhs.gov/guidance-documents.

[10] §§ 93.311 and 93.316.

[11] § 93.217.

[12] *Id.*

[13] §§ 93.217, 93.301(b) and 93.302(b).

[14] § 93.300.

Institutions may assign a Responsible Conduct of Research (RCR) coordinator to assist with these requirements. Some RCR coordinators administer programs that promote research integrity and deter research misconduct. Many times, these programs include activities such as developing, updating, and conducting training related to the responsible conduct of research. Other RCR coordinators assist the RIO with coordinating administrative tasks related to research misconduct proceedings.

ORI understands that concerns and other issues may arise in the course of an institution's management of research misconduct allegations. Institutional officials are encouraged to contact ORI for technical assistance and engage with ORI early during the research misconduct proceedings. If institutional officials are interested in attending ORI's RIO Boot Camp, please reach out to ORI at any time for guidance by calling (240) 453-8400 or emailing AskORI@hhs.gov.

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.

§ 93.200 Accepted practices of the relevant research community.

Accepted practices of the relevant research community means those practices established by 42 CFR part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.

§ 93.217 Institutional Certifying Official.

Institutional Certifying Official means the institutional official responsible for assuring on behalf of an institution that the institution has written policies and procedures for addressing allegations of research misconduct, in compliance with this part; and complies with its own policies and procedures and the requirements of this part. The Institutional Certifying Official is responsible for certifying the content of the institution's annual report, which contains information specified by ORI on the institution's compliance with this part, and ensuring the report is submitted to ORI, as required.

§ 93.218 Institutional Deciding Official.

Institutional Deciding Official means the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer.

§ 93.233 Research Integrity Officer or RIO.

Research Integrity Officer or RIO refers to the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with this part.

§ 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.

§ 93.301 Research integrity assurances.

(a) *General policy*.

(1) An institution that applies for or receives PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, must provide HHS with an assurance of compliance with this part by establishing and then maintaining an active research integrity assurance.

(2) PHS funding components may only authorize release of funds for extramural biomedical and behavioral research, biomedical and behavioral research training, or activities related to that research or research training, to institutions with an active research integrity assurance on file with ORI.

(b) *Research integrity assurance*. The Institutional Certifying Official must assure on behalf of the institution, initially and then annually thereafter, that the institution:

(1) Has written policies and procedures for addressing allegations of research misconduct, in compliance with this part.

(2) Complies with its policies and procedures for addressing allegations of research misconduct.

(3) Complies with all provisions of this part.

§ 93.302 Maintaining active research integrity assurances.

(a) *Compliance with this part*. ORI considers an institution in compliance with this part when it:

(1) Has policies and procedures for addressing allegations of research misconduct according to this part, keeps those policies in compliance with this part, and upon request, provides them to ORI and other HHS components.

(2) Complies with its policies and procedures for addressing allegations of research misconduct.

(3) Complies with all provisions of this part.

(4) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including but not limited to:

(i) Informing the institution's members about its policies and procedures for addressing allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and

(ii) Making its policies and procedures for addressing allegations of research misconduct publicly available.

(b) *Annual report*. An institution must file an annual report with ORI, which contains information specified by ORI, on the institution's compliance with this part. The Institutional Certifying Official is responsible for certifying the content of this report and for ensuring the report is submitted as required.

(c) *Additional information*. Along with its annual report, an institution must send ORI such other information as ORI may request on the institution's research misconduct proceedings covered by this part and the institution's compliance with the requirements of this part.

§ 93.306 Institutional assessment.

(a) *Purpose.* An assessment's purpose is to determine whether an allegation warrants an inquiry.

(b) *Conducting the institutional assessment.* Upon receiving an allegation of research misconduct, the RIO or another designated institutional official must promptly assess the allegation to determine whether the allegation:

(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.

(c) *Assessment results.* (1) An inquiry must be conducted if the allegation meets the three assessment criteria in paragraph (b) of this section.

(2) If the RIO or another designated institutional official determines that requirements for an inquiry are met, they must:

(i) Document the assessment; and

(ii) Promptly sequester all research records and other evidence, consistent with § 93.305(a), and promptly initiate the inquiry.

(3) If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they must keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why the institution did not conduct an inquiry. Such documentation must be retained in accordance with § 93.318.

§ 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.

§ 93.310 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.

§ 93.311 Investigation time limits.

(a) *Time limit for completing an investigation.* An institution must complete all aspects of an investigation within 180 days of beginning it, including conducting the investigation, preparing the draft investigation report for each respondent, providing the draft report to each respondent for comment in accordance with § 93.312, and transmitting the institutional record including the final investigation report and decision by the Institutional Deciding Official to ORI in accordance with § 93.316.

(b) *Extension of time limit.* If unable to complete the investigation in 180 days, the institution must ask ORI for an extension in writing that includes the circumstances or issues warranting additional time.

(c) *Progress reports.* If ORI grants an extension, it may direct the institution to file periodic progress reports.

(d) *Investigation report.* If the investigation takes longer than 180 days to complete, the investigation report must include the reasons for exceeding the 180-day period.

§ 93.314 Decision by the Institutional Deciding Official.

The Institutional Deciding Official is responsible for making a final determination of research misconduct findings. This determination must be provided in a written decision that includes:

(a) Whether the institution found research misconduct and, if so, who committed the misconduct; and

(b) A description of relevant institutional actions taken or to be taken.

§ 93.316 Transmittal of the institutional record to ORI.

After the Institutional Deciding Official has made a final determination of research misconduct findings in accordance with § 93.314, the institution must transmit the institutional record to ORI. The institutional record must be consistent with § 93.220 and logically organized.