# GUIDANCE

*for*

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

## Small Institutions

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Research Integrity (ORI)
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This guidance document is provided by 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 small institutions, according to the U.S. Public Health Service (PHS) research misconduct regulation at 42 CFR Part 93. 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 (HHS), 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) revised its Public Health Service Policies on Research Misconduct regulation (42 CFR Part 93). Under the 2024 regulation, "[s]mall 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."[1] This guidance document clarifies how small institutions can comply with 42 CFR Part 93.

ORI requires all institutions to conduct research misconduct proceedings in a thorough, competent, objective, and fair manner. This requirement includes 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.[2] Some institutions may be too small to conduct research misconduct proceedings as required by 42 CFR Part 93 without actual or apparent conflicts of interest.[3] The PHS regulation includes provisions for small institutions to address these issues in complying with its requirements.

# Small Institutions' Research Integrity Assurances

All institutions applying for or receiving PHS funds for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training are required by HHS to establish and maintain an active research integrity assurance with ORI.[4] This assurance typically stipulates that the institution:

- Submits to ORI written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93.
- Complies with its policies and procedures for addressing allegations of research misconduct.
- Complies with all provisions of 42 CFR Part 93.

Because small institutions typically lack resources to develop and implement policies and procedures to comply with the PHS regulation, small institutions may submit a Small Institution Statement to ORI instead of written policies and procedures, upon approval by ORI.[5] Small institutions that choose not to seek approval to submit a Small Institution Statement must develop written policies and procedures that comply with 42 CFR Part 93. Such institutions may consult ORI's guidance on Writing Policies and Procedures for Handling Allegations of Research Misconduct and ORI's Sample Institutional Policies & Procedures for Addressing Allegations of Research Misconduct.[6]

[1] § 42 CFR 93.240
[2] § 93.300(b).
[3] § 93.240.
[4] § 93.301(a)(1).
[5] § 93.303(a).
[6] These resources can be downloaded from the ORI website at ori.hhs.gov.

# The Small Institution Statement

By submitting a Small Institution Statement, the institution agrees to report all allegations to ORI. ORI or another appropriate HHS entity will work with the institution to advise on a regulation-compliant process for handling allegations that is appropriate for their institutional setting.[7] If a small institution has or believes that it has a conflict of interest during any phase of a research misconduct proceeding, it may contact ORI for guidance.[8]

In addressing conflicts of interest 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. 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.[9]

# How to Qualify as a Small Institution

ORI considers a small institution one that is too small to conduct research misconduct proceedings without an actual or apparent conflict of interest, if an allegation were to emerge. For example, a small institution may have difficulty convening an investigation committee because the institution's small number of members are involved with most aspects of institutional work—including those involved in the alleged research misconduct. To qualify as a small institution, the institution must designate an Institutional Certifying Official, who is responsible for assuring on behalf of an institution that it has a process for addressing allegations of research misconduct that comply with 42 CFR Part 93.[10] If an institution already has a Small Institution Statement on file, it must submit an annual assurance report with an attached Small Institution Statement for six years following the final disbursement of PHS funds.[11] If an institution does not already have an assurance on file with ORI and thinks it may qualify as an ORI-designated small institution, the Institutional Certifying Official can:

- Open the link to the Application for research integrity assurance form on the ORI website.
- Complete the form online and check the box, *This institution qualifies as a small institution and has attached a Small Institution Statement*, which will open the Small Institution Statement.
- Fill out the Small Institution Statement.
- Submit the completed online application.

[7] § 93.303(c).
[8] § 93.303(d).
[9] § 93.305(f).
[10] § 93.217.
[11] § 93.104(a). ORI requires institutions to provide an annual report that details any research misconduct allegations received involving PHS-supported research for a six-year period. This is why institutions must file annual reports for six years following the final disbursement of PHS funds.

ORI will review the institution's Small Institution Statement and notify the institution whether ORI has approved the statement.[12] ORI may request more information from the institution to make its decision. If ORI determines that the institution does not qualify as a small institution, the institution must submit written policies and procedures that comply with 42 CFR Part 93.[13]

# If the Size of a Small Institution Changes

It is advisable for small institutions to notify ORI in a timely fashion if the number of institutional members increases in a way that may affect their status as a small institution. ORI will advise them on how to proceed in light of their larger size.

With regard to responding to research misconduct allegations, ORI understands that issues may emerge on a case-by-case basis. 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 small institutions, please reach out to ORI at any time for guidance by calling (240) 453-8400 or emailing ORI_Assurance@hhs.gov.

[12] § 93.303(a).
[13] §§ 93.300(a), § 93.301(b), 93.302(a)(1), and 93.304.

# Pertinent Sections of 42 CFR Part 93 (2024)

## § 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.

## § 93.219 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.

## § 93.233 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.

## § 93.240 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.

## § 93.301 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.

## § 93.303 Research integrity assurances for small institutions.

(a) Small institutions may file a Small Institution Statement with ORI in place of the institutional policies and procedures required by §§ 93.300(a), 93.301, and 93.304, upon approval by ORI.

(b) The Small Institution Statement does not relieve the institution from complying with any other provision of this part.

(c) By submitting a Small Institution Statement, the institution agrees to report all allegations of research misconduct to ORI. ORI or another appropriate HHS office will work with the institution to develop and/or advise on a process for handling allegations of research misconduct consistent with this part.

(d) If a small institution has or believes it has a conflict of interest during any phase of a research misconduct proceeding, the small institution may contact ORI for guidance.

## § 93.304 Institutional policies and procedures.

Institutions seeking an approved research integrity assurance must have written policies and procedures for addressing allegations of research misconduct. Such policies and procedures must:

(a) Address and be consistent with all applicable requirements pertaining to institutional responsibilities included in this part;

(b) Include and be consistent with applicable definitions in this part; and

(c) Provide for all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

## § 93.305 General conduct of research misconduct proceedings.

(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.