GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Sub-Awardee Assurances

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 sub-awardee assurances 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). This updated regulation clarified the way sub-awardee institutions establish and maintain a research integrity assurance to remain compliant with the regulation. Sub-awardees are institutions that receive PHS support for biomedical or behavioral research and/or related activities through the primary recipient of PHS funds or a pass-through entity. A subaward may, for example, be provided through a legal agreement with a primary awardee of a PHS grant, including an agreement that a pass-through entity considers a contract.

The updated regulation specifies that all recipients of PHS support, including sub-awardees, must establish and maintain an active research integrity assurance with ORI.[1] A research integrity assurance is established when an Institutional Certifying Official assures, on behalf of the institution, that the institution:

- Has 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; and
- Complies with all provisions of 42 CFR Part 93.[2]

To establish a research integrity assurance with ORI, sub-awardees should complete and submit the Research Integrity Assurance Establishment form (see below). As needed, institutions may be required to revise their policies and procedures to bring them into compliance with 42 CFR Part 93.

Once a sub-awardee has established a research integrity assurance with ORI, they keep it active by completing and submitting the Research Integrity Assurance and Annual Report on Possible Research Misconduct form between January 1st and April 30th each year.[3] All recipients of PHS funding, including sub-awardees, should use the Annual Report System on the ORI website to submit their annual report and research misconduct policies and procedures.[4]

Establishing a Research Integrity Assurance

The Research Integrity Assurance Establishment form is available on the ORI website.[5] The form requires sub-awardees to provide general information about the institution and the PHS funds that have been awarded. It also includes an assurance, confirming that the institution has policies and procedures in place to address allegations of research misconduct, which must comply with 42 CFR Part 93. The form requires contact information for institutional official(s) assigned to address research misconduct matters.

[1] 42 CFR §§ 93.102(b)(6) and 93.301(a)(2).
[2] §§ 93.301 and 93.302.
[3] § 93.302(b).
[4] The login for this system may be found at https://ori.hhs.gov/arprm/Login.php.
[5] This form will be available in January 2026.

Additionally, the Research Integrity Assurance Establishment form requires sub-awardees to upload a copy of their research misconduct policies and procedures. Submitting the institution's policies and procedures is mandatory, unless the sub-awardee believes it qualifies 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 more information about how to qualify as a Small Institution, and about how to seek ORI's approval to submit a Small Institution Statement to ORI in lieu of developing written policies and procedures, please see the Small Institutions Guidance document at https://ori.hhs.gov/guidance-documents.

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

Pertinent Sections of 42 CFR Part 93 (2024)

§ 93.102 Applicability.

(a) Every extramural or intramural 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 comply with this part.

(b) This part applies to allegations of research misconduct involving:

(1) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, biomedical or behavioral research training, or activities related to that research or research training;

(2) PHS-supported biomedical or behavioral extramural or intramural research;

(3) PHS-supported biomedical or behavioral extramural or intramural research training programs;

(4) PHS-supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information;

(5) Research records produced during PHS-supported research, research training, or activities related to that research or research training; and (6) Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in an awarded grant, contract, cooperative agreement, subaward, or other form of PHS support.

(c) This part does not supersede or establish an alternative to any applicable statutes, regulations, policies, or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or addressing whistleblowers and/or retaliation.

(d) This part does not supersede or establish an alternative to the HHS suspension and debarment regulations set forth at 2 CFR part 180, as implemented by HHS at 2 CFR part 376; and 48 CFR part 9, subpart 9.4, as supplemented by HHS at 48 CFR part 309, subpart 309.4. The Suspension and Debarment Official SDO and ORI may coordinate actions to the extent consistent with the SDO's and ORI's respective authorities. Such coordination includes jointly issuing notices or seeking settlements of actions and proceedings.

(e) This part does not prohibit or otherwise limit how institutions handle allegations of misconduct that do not fall within this part's definition of research misconduct or that do not involve PHS support.

§ 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.