GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Writing Policies and Procedures for Addressing Allegations of Research Misconduct

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
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This guidance document is a statement of general applicability. It represents the Office of Research Integrity's current view of the most effective way to approach writing institutional policies and procedures for addressing allegations of research misconduct that satisfy the requirements of the Public Health Service (PHS) regulation 42 CFR Part 93. This guidance is intended for extramural or intramural institutions applying for or receiving PHS support for biomedical or behavioral research, biomedical or behavioral training, and/or related activities. The contents of this document do not have the force of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

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Introduction

This guidance document has been prepared by the U.S. Department of Health and Human Services (HHS) Office of Research Integrity (ORI), in connection with the U.S. Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93) published on September 17, 2024. This guidance is intended for institutions, Institutional Certifying Officials, and any staff members responsible for developing, reviewing, and maintaining the institutional policies and procedures required by 42 CFR Part 93.[1]

This document is purely informational and does not establish legal obligations for the United States or its agents, officers, or employees. Instead, it describes ORI's current thinking on developing policies and procedures for responding to allegations of research misconduct under the PHS regulation and should be viewed only as a resource. The use of the word *should* in this guidance means that the actions are recommendations. The use of the word *must* in this guidance refers to a requirement set forth by the PHS regulation.

Background and Discussion

Extramural and intramural institutions that apply for or receive PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training must have written policies and procedures for addressing allegations of research misconduct that meet the requirements of the PHS regulation.[2]

The PHS regulation offers institutions a degree of flexibility regarding the format and details of their written policies and procedures to enable them to create a written document that meets their own needs. For instance, some institutions may choose to establish policies related to promoting research integrity and addressing research misconduct in the format of a stand-alone document, separate from their procedures for responding to allegations of research misconduct. Separating policies and procedures in this way can facilitate institutions' obligation to comply with varying reporting requirements from different funding components. This separation is acceptable as long as the institution also provides ORI with their institutional procedures. That is, the policies and procedures may be separated into two distinct documents or integrated into one; regardless, ORI needs to review both the policies and procedures to confirm institutional compliance with 42 CFR Part 93.

ORI has developed a Sample Policies and Procedures document. Its structure could enable institutions to establish their research integrity and research misconduct policies while retaining flexibility to update their PHS-funded research misconduct procedures as needed (and even add procedures for non-PHS funded research, if they so choose). ORI's Sample Policies and Procedures document is not intended to set a standard or expectation for institutional policies and procedures; it simply provides this proposed structure for institutions that may benefit from such flexibility.

[1] § 93.300(a) and § 93.301(b)(1).
[2] § 93.300(a).

If your institution adapts ORI's Sample Policies and Procedures to create your own institutional policies and procedures, keep in mind that your final document must comply with 42 CFR Part 93. Also, using ORI's Sample Policies and Procedures for your own policies and procedures does not guarantee that ORI will find your institution compliant with 42 CFR Part 93 should your institution address an allegation of research misconduct.

ORI does not dictate the way institutions format their policies and procedures, but to be compliant with the PHS regulation, institutions' policies and procedures must:

- Address and be consistent with all applicable requirements in the PHS regulation pertaining to institutional responsibilities.[3]
- Include and be consistent with applicable definitions in the PHS regulation (see further explanation below).

Developing Detailed and Specific Content

ORI does not mandate that policies and procedures be written verbatim from the PHS regulation. In fact, if an institution's written policies and procedures simply restate the relevant portions of the PHS regulation, they may not provide sufficient detail to be practically useful for the institutional officials conducting research misconduct proceedings. Developing relevant content for written policies and procedures involves a comprehensive and critical assessment of the institution's unique mission, operations, and organizational structure, while adhering to requirements of 42 CFR Part 93.

Ideally, written policies for responding to allegations of research misconduct should be consistent with an institution's overall mission and organizational policy. The institution might consider how to phrase the following key components of their research misconduct policies in a way that complies with the provisions of 42 CFR Part 93 and embodies the organization's core values.[4]

Institutional policies and procedures should have a statement on the institution's commitment to:

- Discourage research misconduct.
- Foster research integrity and the responsible conduct of research.
- Establish mechanisms for reporting alleged research misconduct.
- Respond promptly and appropriately to allegations of research misconduct.
- Establish protocols for handling and securing the institutional record and evidence of possible research misconduct.[5]
- Ensure that institutional policies and procedures meet the requirements of § 93.304.
- Follow institutional policies and procedures when responding to allegations of research misconduct in PHS-supported research.
- Ensure that institutional policies and procedures are publicly available (e.g., on a website or via a designated institutional official with contact details).

[3] § 93.304.
[4] § 93.300.
[5] § 93.318.

Institutional policies and procedures should have a scope and applicability section, which should summarize the PHS regulation's specifications at § 93.102. Institutional policies and procedures typically also have a section for definitions of applicable terms; an institution may include definitions beyond those described in the 42 CFR Part 93, but if an institution includes a term defined in this PHS regulation, it must use that specific definition.

Determining How to Include Required Elements

There is a certain degree of leeway with regard to setting policies around ORI's required elements. For instance, some institutions prefer to include a definitions list in their written procedures, rather than in the policies. Other institutions may choose to add it as an appendix. Some institutions detail the roles and responsibilities (e.g., Research Integrity Officer and committee member) in their policy statement even though this is not a regulatory requirement.

Institutions are responsible for ensuring that specific responsibilities are carried out in compliance with the PHS regulation, but they have discretion in whom they appoint to carry out particular duties provided the person's appointment complies with the PHS regulation (i.e., the appointee has appropriate expertise, discloses potential conflicts of interest, and acts in good faith).[6] It is helpful to view your institution's written procedures as a road map: they provide practical, step-by-step instructions for following the specific requirements outlined in the PHS regulation. The written procedures should help anyone who is potentially or directly involved in research misconduct proceedings understand how to carry out their duties in a thorough, competent, objective, and fair manner.[7] The policies and procedures should be sufficiently detailed and clear to be useful for all participants, including prospective complainants, respondents, witnesses, committee members, support staff, and other relevant personnel.

Institutions may include in their policies and procedures more detail, explanatory material, and requirements beyond those required by the PHS regulation, excepting content that contravenes any PHS regulatory requirements.[8] For instance, while the definition of plagiarism in the PHS regulation does not include self-plagiarism or authorship or credit disputes, some institutions may prefer to include such concerns in their own guidelines.

Institutions may also consider writing PHS regulation-compliant policies and procedures as an opportunity to invite discussion and build consensus on such requirements. We have highlighted a few potential topics for discussion:

- Addressing confidentiality during and after research misconduct proceedings in § 93.106
- Making all reasonable and practical efforts to protect or restore the reputation of respondents not found to have committed research misconduct in § 93.304(c)
- Sequestering, securing, inventorying, and maintaining research records and giving respondents access in § 93.305(a), (b), (c)

[6] § 93.214(b); § 93.305(f); § 93.310(f).
[7] § 93.300(b).
[8] § 93.319.

- Protecting the positions and reputations of good faith complainants, witnesses, and committee members in § 93.300(d).
- Protecting good faith complainants, witnesses, and committee members from retaliation by respondents and other institutional members in § 93.300(d).
- Ensuring 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 in § 93.300(f).
- Ensuring 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 complainants, respondents, or witnesses in § 93.300(b).

Handling Provisions Where Institutions Have Discretion

The PHS regulation also includes some provisions where institutions have broad discretion; these provisions typically are expressed as "institution(s) may..." Your institution may choose to include all, some, or none of these provisions in its policies and procedures. If choosing to write procedures for one or more of these provisions, your institution should consider:

"If-Then" Provisions. In some cases, if institutions choose to do something, they must do it in a certain way. For example (boldface added for emphasis):

"The institution is not required to notify a complainant whether the inquiry found that an investigation is warranted. The institution may, but is not required to, provide relevant portions of the report to a complainant for comment. **If an institution provides notice to one complainant in a case, [then] it must provide notice, to the extent possible, to all complainants in the case.**"[9]

Downstream Impact. Institutions should think about whether to include a given provision not required by the PHS regulation, given its impact during subsequent stages of the research misconduct proceedings. For example, the PHS regulation does not require institutions to conduct interviews during the inquiry.[10] If an institution chooses to conduct interviews at any point prior to the investigation, they are not required to record them. However, witnesses or respondents may share valuable information in the early phases of the misconduct proceedings that institutions would like to refer to later as potential evidence. For instance, witnesses may change their narrative over the course of a research misconduct proceeding. In such instances, a record of conflicting statements may be helpful to demonstrate such inconsistencies.

[9] § 93.308(b).
[10] § 93.307(e)(3).

A Few Helpful Reminders

Over the years, ORI has observed that some institutional policies and procedures omit key provisions. These omissions can lead to inconsistencies or regulatory violations when the institution conducts its research misconduct proceedings. Listed below are some commonly omitted provisions:

- Six-year limitation on allegations and exceptions to the six-year limitation in § 93.104
- Evidentiary standards, including preponderance of evidence and burden of proof in § 93.105
- Confidentiality in § 93.106
- Sequestration of research records; maintenance of and access to sequestered records in § 93.305(a),(b), and (c); § 93.318
- Notifying respondents before, during, and at closure of proceedings in § 93.307(c), § 93.308; § 93.310 (c)
- Giving respondents the opportunity to comment on inquiry and investigation reports and considering those comments in § 93.307(g)(3), § 93.312, and § 93.313(j)
- Notifying ORI on the decision to initiate an investigation in § 93.309 and § 93.317
- Pursuing leads under § 93.310(j)
- Criteria and time limitations for each phase of the proceedings in § 93.306(b), § 93.307(a), § 93.307(f)(1), § 93.307(h), § 93.311(a)

Conclusion

ORI acknowledges that conducting research misconduct proceedings may be complex and difficult to navigate. However, well-written policies and procedures can serve as an invaluable resource when these challenges arise. Moreover, policies and procedures help ensure that an institution's research misconduct proceedings will be handled in a thorough, competent, objective, and fair manner.

For assistance with writing institutional policies and procedures for responding to allegations of research misconduct involving PHS-supported biomedical and behavioral research, research training, and related activities, please contact ORI-ComplianceReviews@hhs.gov