Decision Points:

Considerations for Institutions in Implementing the 2024 PHS Research Misconduct Rule

(September 2025, v. 1)

Decision Points in the 2024 PHS Research Misconduct Rule (42 CFR Part 93)

How to Use this Document

As institutions develop new research misconduct policies and procedures to comport with the 2024 PHS Research Misconduct Rule ("2024 Rule"), they should consider provisions of the 2024 Rule that offer flexibility in how to address certain regulatory requirements.

This document highlights and discusses provisions of the 2024 Rule that present these flexibilities. Institutions should consider these flexibilities and determine what path their institution will take in addressing them and how to best incorporate these choices in their policies and procedures.

Note that this document only address flexibilities that are new to the 2024 Rule, and there are also flexibilities from the 2005 version of the PHS Research Misconduct Rule that carried over into the 2024 Rule.

Decision Points: Sections Covered

Subpart	Section	Description
A	§ 93.106 (a)	Confidentiality
B	§ 93.218	Institutional Deciding Official
C	§ 93.300 (a)	Written policies
	§ 93.303	Small institutions
	§ 93.304 (c)	Protect and store reputations
	§ 93.305 (d)	Multiple respondents
	§ 93.305 (f)	Review panel composition
	§ 93.306 (b)	Institutional assessment
	§ 93.307(e)(2)	Conducting inquiry
	§ 93.310 (g)	Interviews
	§ 93.312 (b)	Draft Review by Complainant
	§ 93.314	Final determination
	§ 93.315 (a)	Institutional appeals
	§ 93.316	Institutional record to ORI
	§ 93.317 (a)	All credible and significant leads
	§ 93.317 (b)	Admission
	§ 93.318 (a)	Retention and custody of the institutional record

Decision Points: Required Written Policies & Procedures

Written Policies

Key Issue: Institutions must have written policies & procedures that meet the 2024 Rule's requirements. [42 CFR 93.300(a)].

- **Decision Points**:
- What requirements will the institution address in policy vs. procedures? (See breakdown between policy and procedure in ORI's Sample Policies and Procedures for Addressing Allegations of Research Misconduct.).
- What are the pros and cons of incorporating **all** the 2024 Rule's requirements in policy in view of institutional processes for adopting/modifying institutional policies vs. institutional procedures?

Small Institution Option

Key Issue: With ORI approval, a small institution may file a Small Institution Statement with ORI in lieu of institutional policies & procedures. [42 CFR 93.240 & 93.303].

- **Decision Points**:
- Does the institution meet the qualifications for designation as a Small Institution?
- If so, how does the institution weigh the benefits of not being required to develop institutional policies and procedures against the obligations under Small Institution Statement to (a) report all allegations of research misconduct to ORI; and (b) work with ORI (or another HHS office) on a process for handling allegations of research misconduct consistent with all other provisions of the 2024 Rule?

Decision Points: Roles & Responsibilities

Responsibility for Conducting Proceedings

Key Issues: •Institution may use (a) convened committee of experts; (b) consortium; or (c) other person to conduct research misconduct proceedings. [42 CFR 93.305(f)].

•RIO (or other designated official) is specifically permitted to conduct (a) assessment and (b) inquiry, with option to use subject matter experts, if needed. [42 CFR 93.306(b), 93.307(e)(2)].

- **Decision Points:**
- Who will be assigned the responsibility under institution's policy and procedures to conduct (a) assessment; (b) inquiry; and (c) investigation?
- Will the institution take advantage of flexibility to have RIO conduct both assessment and inquiry?
- Will the institutional policy make a fixed assignment of responsibility (e.g., RIO always conducts inquiry) or incorporate flexibility as to how responsibility will be assigned at one or more stages of the proceedings (e.g., RIO or committee may conduct inquiry)?
- If there is flexibility, who will make determination as to how responsibility will be delegated?
- If a committee is used, will it be a standing or *ad hoc* committee?

Role of the Institutional Deciding Official

Key Issues: •Under the 2024 Rule, the Institutional Certifying Official and the Institutional Deciding Official have distinct responsibilities. [42 CFR 93.217-.218]. •The Institutional Deciding Official's role is limited to making a final determination of research misconduct findings and must be a different individual than the RIO. [42 CFR 93.218 & 93.314].

- **Decision Points**:
- Will the Institutional Certifying Official and Institutional Deciding Official be the same or separate individuals?
- Will the Institutional Deciding Official's role be limited to the investigation phase?
- Will the policy require the Institutional Deciding Official to give specific consideration or deference to the findings of committee/consortium/designated individual that conducted the investigation (or other proceeding phase) for which official is making a decision?

Decision Points: General Requirements for All Phases of Proceedings

Confidentiality

Key Issue: •During conduct of proceedings, institution may disclose identity of respondents, complainants, and witnesses to those institution determines has a need to know consistent with a fair/thorough proceeding and applicable law.[42 CFR 93.106(a)].

- **Decision Points**:
- Will the institution define "need to know" in its written policy? If so, how should it be defined?
- Will the institutional policy include (a) illustrative examples; and/or (b) a definitive list of "need to know" circumstances?

Admissions

Key Issues: •ORI must be notified if institution closes proceedings early on the basis of an admission or settlement. [42 CFR 93.317(a)]. •Admissions must be in writing, signed by respondent, meet all elements for a research misconduct finding under 93.103, and provided to ORI prior to closure, along with institutional statement describing how scope of misconduct was fully addressed by admission. [42 CFR 93.317(b)].

Decision Points:

- When will notification of closure on basis of admission be provided to ORI, i.e., what triggers notification?
- How will the institution assess whether scope of misconduct is fully covered by the admission?
- Will the institution develop an admission template that sets forth all required elements for an admission?

Decision Points: General Requirements for All Phases of Proceedings

Institutional Record

Key Issues: •2024 Rule contains specific requirements for development, maintenance, and provision to ORI of Institutional record [42 CFR 93.220 & .316]. •All sequestered evidence, regardless of whether it is part of the Institutional Record, must be maintained for prescribed period. [42 CFR 93.318(a)].

- How will the institution incorporate 2024 Rule's concept of Institutional Record into policies and procedures?
- How will the Institutional Record be logically and consistently organized? Will there be a template or content framework for the Institutional Record?
- How and where will the institution securely store sequestered evidence, including physical objects, for the short-term and long-term?
- How will the institution address return and/or destruction of sequestered evidence after 7-year retention period has expired?

Interviews

Key Issues: •Interviews of respondents, complainants and witnesses may occur at various stages of the proceedings. [93 CFR 93.307 & 93.310(g)]. •There are additional requirements for interviews at the investigation phase, including required recording and transcription, attachment of numbered exhibits, opportunity for interviewee to correct transcript, prohibition of respondent's attendance at witness interviews, and requirement that transcript of witness interviews be provided to respondents, and inclusion of transcripts in Institutional Record. [42 CFR 93.309, 93.310(g), 93.313].

- How will the institution define what activities constitute interviews? All meetings with any parties? A limited subset of such meetings?
- Will the institution record/transcribe interviews that take place at phases of the proceedings other than the investigation phase?
- What mechanisms will the institution use for transcription and recording (e.g., court report, automated transcription application)?

Decision Points: General Requirements for All Phases of Proceedings

Pursue Leads

Key Issues: •Institutions must pursue all significant issues and credible allegations of research misconduct. [42 CFR 93.317(a)]. •Allegations are "disclosures of possible research misconduct through any means of communication and brought directly to the attention institutional or HHS official." [42 CFR 93.203].

- **Decision Points:**
- How will the institution incorporate 2024 Rule's definition of allegation into its evaluation of "Clare Francis" or "PubPeer" communications?
- What standards will institutions use to evaluate "significance" and "credibility"?

Multiple Respondents

Key Issue: •If institution identifies additional respondents during inquiry or investigation, it is not required to conduct a separate inquiry/investigation but must provide respondent notice and opportunity to respond. [42 CFR 93.305(d)].

- **Decision Points**:
- Will the institution conduct separate inquiry/investigation if a respondent is added?
- Will policy/procedures be definitive or flexible on this point? If flexible, what criteria will be used to make decision and who will decide?
- If separate inquiry/investigation is provided, will there be a separate committee/designated person? Separate report?

Protect & Restore Reputations

Key Issue: •If requested, and as appropriate, institution must provide reasonable and practical efforts to protect or restore reputation of persons alleged to have engaged in research misconduct, but for whom there were no findings. [42 CFR 93.304(c)].

- **Decision Points**:
- Will the institution's policy or procedures include a framework and/or examples of what actions the institution may take to protect/restore reputations and when the actions may take place?

Decision Points: Investigation Conclusion & Appeal

Investigation Report

Key Issue: The institution may provide the complainant with a copy of the draft investigation report or relevant portions of that report for comment, which must be submitted within 30 days of receipt thereof. [42 CFR 93.312(b)].

- **Decision Points**:
- Will the institution afford the complainant the right to review the investigation report (or portions thereof) and make comments?
- If so, will the right be afforded to all complainants, or a subset of complainants (e.g., identified complainants that were witnesses in the investigation) and will complainants be limited as to what they may comment on (e.g., accuracy of the description of their testimony)?
- How will the institution consider/utilize any comments provided by the complainant?

Appeal

Key Issue: If respondent appeals an institution's findings of research misconduct or institutional actions, the institution must promptly notify ORI. [42 CFR 93.315(a)].

- **Decisions Points:**
- Will the institution's policy include the right of the respondent to appeal a finding of research misconduct, and if so, on what basis may an appeal be made and how will the appeals process work?
- At what point will notification of an appeal be provided to ORI, and who will have the responsibility for making that notice?