



WHOSE GOT GUIDANCE?:

Results from the ARIO/COGR Survey of Research Integrity Officials on the Final ORI Research Misconduct Rule

By Kristin West and Lauran Qualkenbush

On September 17, 2024, the Department of Health Human Services' Office of Research Integrity (ORI) issued an updated version of the Public Health Service (PHS) Policies on Research Misconduct ("Final Rule") (2024). To gauge research integrity personnel's assessment of the Final Rule, the Association of Research Integrity Officers (ARIO) and COGR jointly issued a survey designed to determine which provisions of the Final Rule require additional clarification or guidance from ORI, the research integrity officer (RIO) community ("Community"), or both. COGR and ARIO sent the survey to their members and requested one response per institution. One hundred seventy-seven responses were received, consisting of ninety-one complete responses and eighty-six partial responses.

Key Survey Findings

Overall, survey responders sought additional guidance from ORI, the Community, or both for most newly defined terms and virtually all of the Final Rule's new policy and institutional requirements.

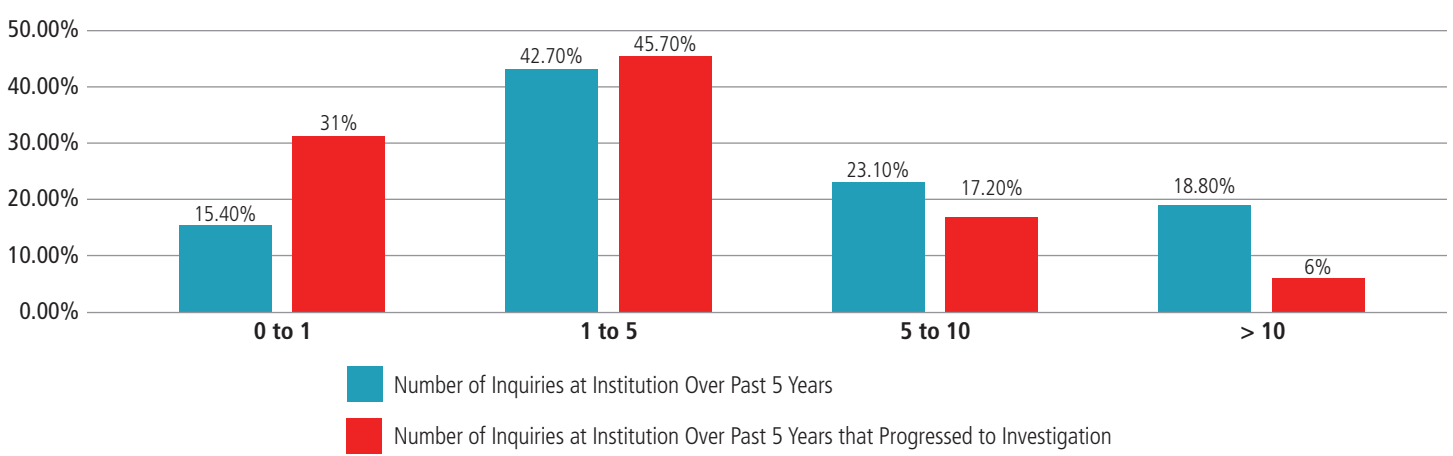
- **Defined Terms:** Responders selected "accepted practices of the relevant research community," "institutional record," and "recklessly" as the terms most requiring additional clarification.
- **Formal Assessment Phase:** Seventy percent of Responders requested guidance on the rule's new formal assessment phase, but they were fairly evenly split on whether that guidance should come from ORI, the Community, or both.
- **Requirements for the Inquiry and Investigation Phases:** Responders identified specifications for developing an institutional record and the requirement to pursue leads as top priorities for ORI and/or Community guidance.
- **Early Implementation:** Fifty-eight percent of responders stated that their institutions would not implement the Final Rule prior to January 1, 2026, the date on its requirements become effective.

Detailed survey demographics and findings are presented in the following graphs and charts.

Survey Demographics

Nearly three-quarters of Responders were from public institutions, and 87.5% of responding institutions were colleges/universities. Sixty-eight percent of individuals who completed the survey were RIOs and over 40% had one to five years of experience handling research misconduct allegations at their institution.

Figure 1. Number of Research Misconduct Inquiries Under PHS Policy at Institution Over Past 5 Years and No. those Inquiries that Progressed to Investigation



Detailed Survey Results

Defined Terms

The Final Rule added eleven newly defined terms. The majority of Responders thought no additional guidance was required for the terms “Institutional Certifying Official” and “Institutional Deciding Official,” but Responders split evenly on whether “Assessment” and “Intentionally” required clarification.

Policy and Institutional Requirements

The Final Rule added significant new policy and process provisions. Figure 3 details provisions for which more than 50% of Responders sought ORI and/or Community guidance. The only provision for which the majority of Responders did not request guidance was the requirement to make research misconduct policies publicly available.

Figure 2. Table of Newly Defined Terms for which >50% of Responders Indicated ORI and/or Community Guidance was Necessary.

Term	Defined Terms for which Majority of Responders Requested ORI and/or Community Guidance (Ranked by Highest to Lowest Overall % of Responders Requesting ORI and/or Community Guidance)			
	Overall % of Responders Requesting Guidance from All Sources	% of Responders Requesting ORI Guidance	% of Responders Requesting Community Guidance	% of Responders Requesting ORI and Community Guidance
Accepted Practices of the Research Community	70%	20%	23.3%	26.7%
Recklessly	66.6%	20.2%	9.5%	36.9%
Institutional Record	58.8%	23.5%	15.3%	20%
Research Record	54.7%	25%	8.3%	21.4%
Administrative Record	52.4%	34.5%	6%	11.9%
Knowingly	51.3%	15.9%	9.8%	25.6%

Figure 3. Table of Policy and Institutional Requirements for which >50% of Responders Indicated ORI and/or Community Guidance was Necessary.

Provision	Provisions for which Majority of Responders Requested ORI and/or Community Guidance (Ranked by Highest to Lowest Overall % of Responders Requesting ORI and/or Community Guidance)			
	Overall % of Responders Requesting Guidance from All Sources	% of Responders Requesting ORI Guidance	% of Responders Requesting Community Guidance	% of Responders Requesting ORI and Community Guidance
Handling allegations involving multiple institutions (§93.305(e))	76.2%	19.0%	15.5%	41.7%
Fostering a research environment that promotes research integrity (§93.300(c))	72.9%	17.6%	21.2%	34.1%
Time limitations, including application of subsequent use exception (§93.104)	69.4%	30.7%	14.8%	23.9%
Sequestration of evidence (§93.305)	66.6%	21.4%	21.4%	23.8%
Handling allegations involving multiple respondents (§93.305(d))	65.4%	20.2%	11.9%	33.3%
Requirements for admission statements (§93.317(b))	61.4%	33.7%	8.4%	19.3%
Confidentiality, including application of need-to-know criteria (§93.106)	61.2%	11.8%	12.9%	36.5%
Use of a committee, consortium, or other person to conduct research misconduct proceedings (§93.305(f))	57.9%	24.1%	13.3%	20.5%
Closing cases at assessment, inquiry, or investigation (§93.317)	55.8%	20.9%	18.6%	16.3%



Inquiry and Investigation Phases

The Final Rule made substantial changes to the inquiry and investigation phases of research misconduct proceedings, but as shown in Figure 4, Responders did not think that additional guidance was warranted for all new provisions.

Nonetheless, Responders sought ORI and/or Community guidance for several new provisions, particularly the requirement to pursue leads and to maintain an institutional record.

How ARIO and COGR Plan to Use the Survey's Results

The survey demonstrates that the individuals who are responsible for developing and administering research misconduct policies and procedures have numerous questions about implementing the Final Rule's terms and requirements. Additionally, it makes clear that individuals are seeking not just ORI' guidance, but guidance from the Community on understanding and implementing the Final Rule. ARIO and COGR plan to communicate the survey results to ORI in an effort to assist the agency in developing guidance materials, and they will also use the results to help shape the Community guidance RIOs have requested. ■

Reference

Public Health Service Policies on Research Misconduct, 89 F.R. 76280 (Sept. 17, 2024) (codified at 42 C.F.R. pt. 93). <https://www.federalregister.gov/documents/2024/09/17/2024-20814/public-health-service-policies-on-research-misconduct>

Figure 4. Table of Inquiry/Investigation Requirements for which >50% of Responders Indicated ORI and/or Community Guidance was Unnecessary.

Requirement	% of Responders that did Not Request Additional ORI or Community Guidance (Ranked by Highest to Lowest Overall % of Responders Requesting ORI and/or Community Guidance)
Inquiry Phase	
RIOs are explicitly permitted to conduct inquiries (§93.307(e)(2)).	63.4%
Notification of whether an investigation is warranted, and relevant provisions of the inquiry report are not required to be provided to complainant. (§93.308(b)).	60%
Persons who may be interviewed as part of the inquiry. (§93.307(e)).	56.1%
No requirement to conduct a separate inquiry when additional respondents are identified at inquiry or investigation. (§93.307(c)).	52.4%
Investigation Phase	
The same investigation committee may investigate multiple respondents with separate determinations and reports. (§93.310(c)(3)).	70%
A complainant is not required to be provided with a copy of the draft investigation report. (§93.312(b)).	64.6%
Respondents may not be present for witness interviews but must receive a copy of the interview transcript. (§93.310(g)(5)).	53.1%
New role of Deciding Official with specified duties. (§93.314).	51.2%

Figure 5. Table of Inquiry/Investigation Requirements for which >50% of Responders Requested ORI and/or Community Guidance.

Requirement	Phase & Corresponding Regulation(s)	Provisions for which Majority of Responders Requested Some Type of Guidance (Ranked by Highest to Lowest Overall % of Responders Requesting ORI and/or Community Guidance)			
		Overall % of Responders Requesting Guidance from All Sources	% of Responders Requesting ORI Guidance	% of Responders Requesting Community Guidance	% of Responders Requesting ORI and Community Guidance
Requirement to pursue leads	Investigation (§93.310(j))	78.6%	33.3%	15.5%	29.8%
Detailed specifications for developing & maintaining institutional record	Inquiry (§§93.220, 93.307(g) & 93.309)	73.7%	32.1%	20.2%	21.4%
Detailed specifications for development, maintenance, & transmittal of institutional record	Investigation (§§93.220, 93.313, 93.316)	59.8%	24.4%	9.8%	25.6%
Detailed specifications for the Investigation report	Investigation (§93.313)	59.6%	22.8%	12.7%	24.1%
Detailed specifications for the Inquiry report	Inquiry (§93.309)	57.8%	28.9%	9.6%	19.3%



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