

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

Executive Summary

During the period October 31, 2024, to November 30, 2024, COGR and ARIO conducted a survey of individuals at research institutions who are responsible for overseeing policies and processes for the review of allegations of research misconduct under the PHS Policies on Research Misconduct (“PHS Policy”).¹ On September 17, 2024, the federal Office of Research Integrity (ORI) published a substantially modified PHS Policy (“[Final Rule](#)”), and the survey was designed to determine which provisions of the Final Rule required additional clarification or guidance from ORI, the research integrity community (“Community”), or both. COGR and ARIO sent the survey to their members and requested one response per institution. One hundred seventy-seven total responses were received consisting of 91 complete responses and 86 partial responses.



Key points from the survey results include the following items:

- **Guidance Required for Most Newly Defined Terms:** More than half of the survey responders (“Responders”) called for additional clarification from ORI and/or the Community for six of the 11 newly defined terms added to the Final Rule. The terms most cited as requiring additional clarification were “accepted practices of the relevant research community,” “institutional record,” and “recklessly.”

¹ 42 C.F.R. Part 93.

- **Responders Sought Additional Guidance/Clarification for All but One of the Final Rule’s New Institutional and Policy Provisions:** The provision on maintaining an institutional research integrity assurance and making research misconduct policies and procedures publicly available was the only requirement most Responders (60.2%) thought did not require further clarification.
- **Responders Split on What Guidance is Needed on New Assessment Process:** Nearly 70% of Responders thought some guidance was needed on the Assessment process, but they split over who should provide that guidance, with 38% calling for either ORI or Community guidance and 31% requesting both ORI and Community guidance.
- **Responders Named Institutional Record Specifications and the Requirement to Pursue Leads as the Top Inquiry/Investigation Provisions for Guidance/Clarification:** Nearly three-quarters of Responders sought additional ORI and/or Community guidance/clarification on the requirements for developing and maintaining an institutional record. Similarly, almost 79% of Responders sought ORI and/or Community guidance on the requirement to pursue leads, with one-third calling for ORI guidance.
- **Most Institutions will Not Implement the Final Rule Before January 1, 2026:** When asked whether they would implement the Final Rule early, 58% of Responders reported they would not.

Detailed Survey Results

SURVEY DEMOGRAPHICS

One hundred seventy-seven institutions responded to the Survey, with 91 complete responses and 86 partial responses. Nearly 73% of the institutions that responded were public institutions and 87.5% of institutions were colleges/universities. Nearly 68% of the individuals that answered the survey questions were research integrity officers (RIOs), with an additional 27% of Responders reporting that they were associate RIOs or otherwise led or supported institutional research integrity efforts. Forty percent of Responders reported having one to five years of experience at their institution in handling allegations of research misconduct under the PHS Policy, with an additional 20% reporting five to ten years of experience. Just over 43% of Responders

reported handling one to five inquiries over the past five years, with 45% of those inquiries continuing to investigation.

Figure 1. Number of Years Responder Has Handled Research Misconduct Allegations under the PHS Policy at Their Institution

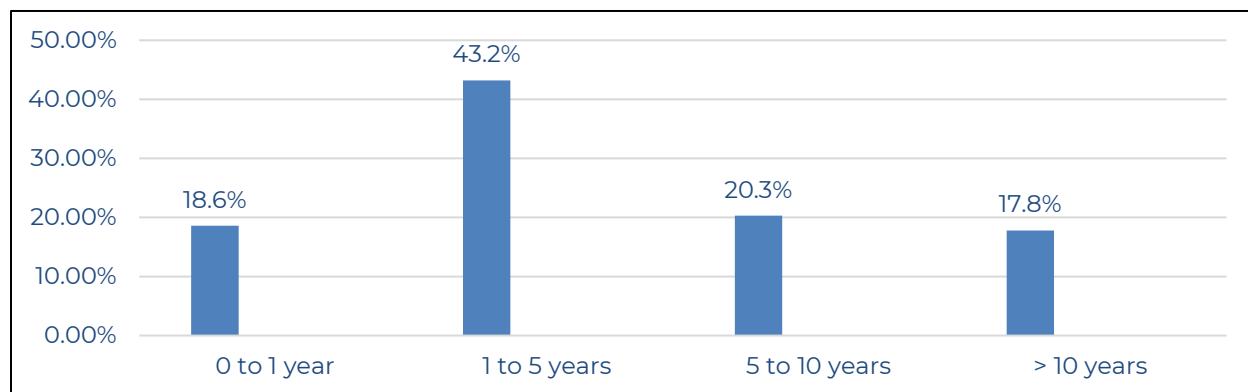
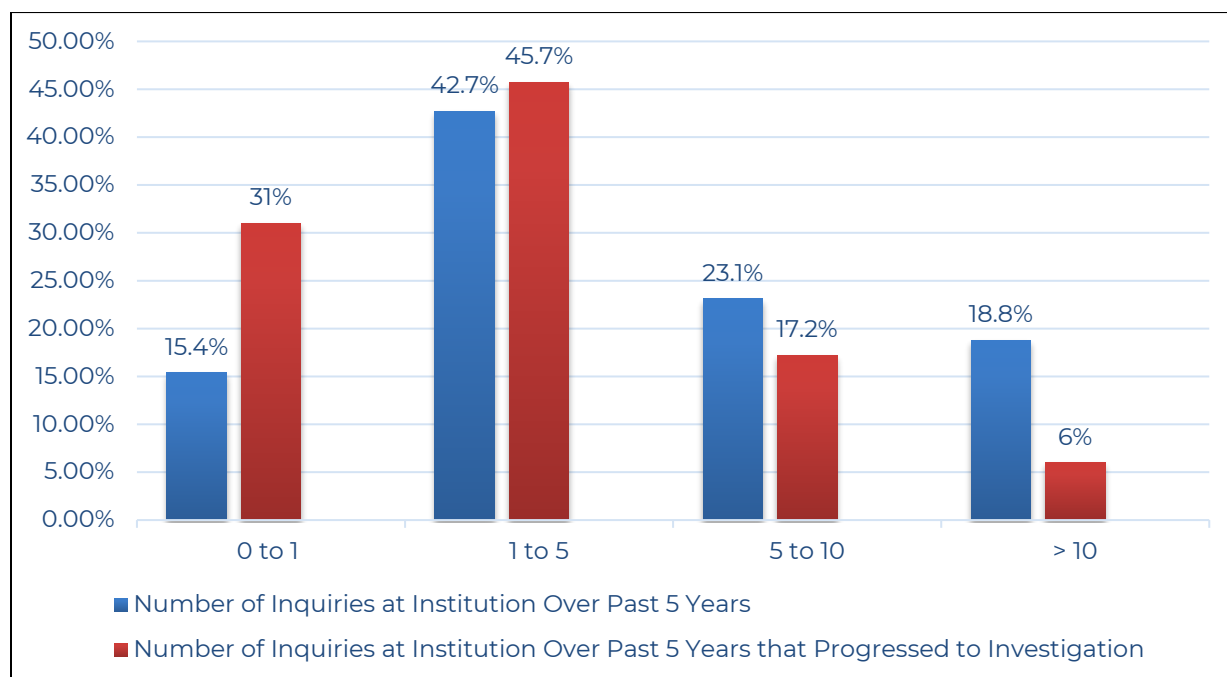


Figure 2. Number of Research Misconduct Inquiries Under PHS Policy at Institution Over Past 5 Years and Number of those Inquiries that Progressed to Investigation



NEWLY DEFINED TERMS ADDED TO FINAL RULE

The Final Rule added 11 newly defined terms. Fifty percent or more of Responders reported that they required no additional guidance or clarification from ORI or the Community for the following five terms:

- Assessment (50.6%)
- Institutional Certifying Official (65.1%)
- Institutional Deciding Official (85.4%)
- Intentionally (50%)
- RIO (94%).

The table below shows newly defined terms added to the Final Rule for which > 50% of Responders indicated that ORI and/or Community Guidance was necessary, ranked from highest to lowest.

Figure 3. 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%

POLICY AND INSTITUTIONAL REQUIREMENTS

The Final Rule added significant new provisions concerning time limitations/subsequent use, confidentiality/need-to-know, fostering an environment that promotes research integrity, maintaining a research integrity assurance and policies/procedures, sequestration, cases involving multiple respondents or multiple institutions, mechanisms for conducting proceedings, closing cases, and admissions. There was only one of these

provisions for which most Responders did not seek ORI and/or Community guidance: the requirement that institutions maintain a research integrity assurance and make policies and procedures for handling research misconduct allegations available to the public.

As summarized in the table below, Responders requested some type of guidance for the other provisions in this category, with both ORI and Community guidance being requested in most cases. Requirements for handling allegations involving multiple institutions and fostering an environment that promotes research integrity were the two provisions that the greatest number of Responders thought required guidance, with calls for ORI and Community guidance being the most prevalent. Several Responders also provided written comments seeking information on how RIOs and ORI view institutional responsibilities in this area.

Responders cited provisions concerning admission statements and time limitations/subsequent use as the requirements that most required ORI guidance. For admissions statements, commenters sought ORI guidance on how institutions must determine and describe the “scope of misconduct” addressed in an admission under §93.317(b). On the issue of subsequent use, Responders commented that ORI should provide guidance on the meaning of the term “use of” in §93.104(b)(1), as well as its expectations for institutional documentation that the exception does not apply.

Figure 4. 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%

ASSESSMENT PHASE

Seventy percent of Responders requested some type of guidance regarding the Final Rule’s new formal Assessment phase, while 30% thought no additional guidance was necessary. Nearly one-third of Responders called for both ORI and Community guidance on Assessment, while 14% requested only ORI guidance and just over 24% sought only Community Guidance.

INQUIRY AND INVESTIGATION PHASES

The Final Rule made several substantial changes to the Inquiry and Investigation phases of research misconduct proceedings. However, as shown in the table below, there were several provisions for which most Responders did not think additional guidance was warranted.

Figure 5. 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 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%

The Final Rule’s new requirements for Inquiry and Investigation phases for which Responders most requested ORI and/or Community were: (1) the requirement to pursue leads; (2) detailed requirements for the institutional record; and (3) detailed requirements for Investigation and Inquiry reports. Overall results are shown in the table below.

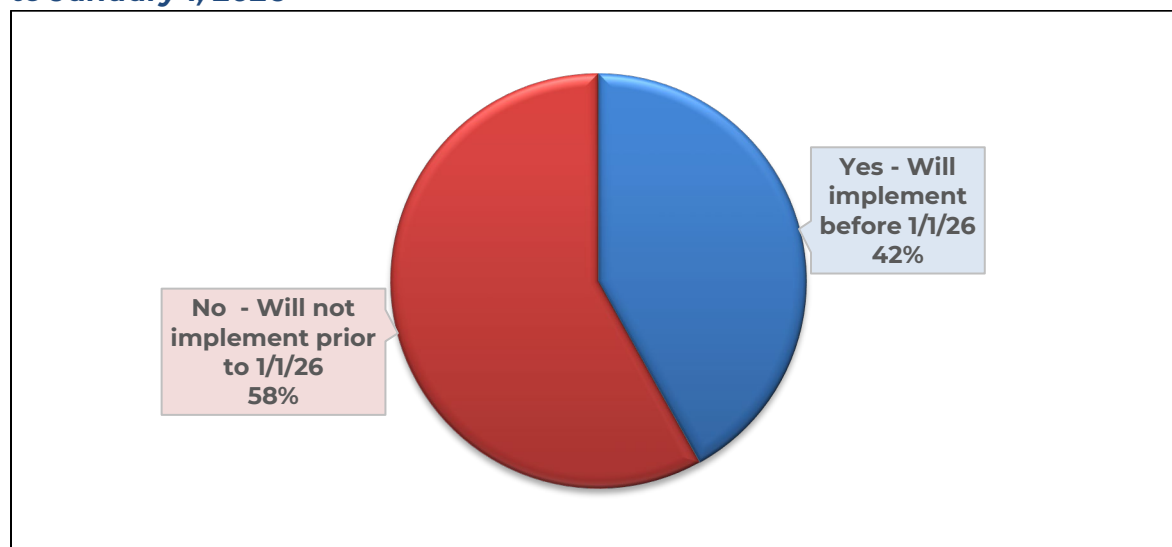
Figure 6. Table of Inquiry/Investigation Requirements for which >50% of Responders Requested ORI and/or Community Guidance.

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%

TIMELINE FOR IMPLEMENTATION OF FINAL RULE

Almost 60% of Responders reported that they will not implement the Final Rule prior to January 1, 2026, the date on which all its requirements are applicable.

Figure 7. Percentage of Responders who Will/Will Not Implement Final Rule Prior to January 1, 2026



ANALYSIS OF ADDITIONAL COMMENTS

Several Responders provided written comments on additional details of the Final Rule for which they would like ORI to provide guidance and clarification.

- The Final Rule requires that institutions provide respondents with transcripts of witness interviews. Six Responders were concerned that this requirement may lead to retaliation against witnesses, and requested ORI guidance on how to protect witnesses, including permissible transcript redactions.
- Two Responders noted the administrative burden and expenses associated with the maintenance of research misconduct proceeding records, and they sought ORI guidance on record retention requirements when a proceeding is closed at Assessment or Inquiry.
- Two commenters requested additional clarification regarding §93.105(b), *Burden of Proof* and how the failure to provide research records can be used as evidence of research misconduct.
- Two commenters sought guidance on quantifying and managing timelines for the conduct of complex cases, including management of requests for/and objections to extensions.

Additionally, individual Responders requested ORI information/guidance on the following topics/questions:

- Whether ORI will make its Assurance Database open to the public?
- Evaluating and responding to affirmative defenses and mitigating factors.
- How the Final Rule will apply to cases that are in process on January 1, 2026, and how institutions should address the possibility of handling cases under the new and the prior version of the rule?
- Managing respondents who refuse to be interviewed or to respond to requests from inquiry and investigation committees.
- Addressing respondents and complainants who do not act in good faith.
- How institutions should address varying federal agency requirements for research misconduct policies, e.g., should institutions have separate PHS and NSF research misconduct policies/procedures?

Conclusion

The Final Rule made substantial changes to the requirements for the conduct of Research Misconduct proceedings governed by PHS regulations. The survey demonstrates that the individuals responsible for developing and administering research misconduct policies/procedures have numerous questions about the Final Rule's terms and requirements. Fortunately, the survey also illustrates that community members have, for the most part, coalesced around those provisions of the Final Rule that require clarification/guidance, as well as the need for both ORI and Community guidance in these areas.

COGR and ARIO thank all the institutions and personnel who took the time to participate in this survey. They will use the results from the survey to shape communications with ORI and to develop information and tools to assist institutions as they implement the Final Rule.

If you have any questions regarding this survey, please contact Kris West, COGR's Director of Research Ethics and Compliance at kwest@cogr.edu or Luran Qualkenbush, ARIO President at lhane@northwestern.edu.

About ARIO & COGR

ARIO was officially established in 2016 to provide a dedicated platform for RIOs, their staff, and general counsel to discuss, develop, and share best practices and strategies for handling research misconduct allegations and promoting ethical research.

Founded in 1948, COGR is the national authority on federal policies and regulations affecting U.S. research institutions. COGR provides a unified voice for over 220 research universities, academic medical centers, and research institutes. It advocates for effective and efficient research policies and regulations that maximize and safeguard research investments and minimize administrative and cost burdens.