



December 12, 2023

Submitted electronically to: <https://www.regulations.gov>

Sheila Garrity, Director
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Comments on Public Health Service Policies on Research Misconduct Notice of Proposed Rulemaking

Dear Ms. Garrity:

COGR is an association of over 200 public and private United States research universities and affiliated academic medical centers and research institutes. We focus on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient and effective regulation that safeguards research and minimizes administrative and cost burdens. We write today to comment in response to the Office for Research Integrity's (ORI) *Notice of Proposed Rulemaking on the Public Health Service Policies on Research Misconduct* published in the October 6, 2023, Federal Register. [[88 FR 69583](#)] (the "NPRM").

Ensuring the responsible and ethical conduct of research – free from fabrication, falsification, and plagiarism – is a primary responsibility and focus of every academic institution that conducts research, regardless of funding source. Given the prominence of Public Health Service (PHS) funding for much of the research conducted at many U.S. universities, COGR member institutions have first-hand experience in understanding how the current 2005 PHS Policies on Research Misconduct [[42 CFR Part 93](#)] ("2005 Regulations") have worked in practice. Moreover, COGR, in consultation with its member institutions, is uniquely positioned to assess which portions of the 2005 Regulations require clarification and/or modification. Accordingly, we appreciate ORI's solicitation of stakeholder input regarding the NPRM's proposed changes to the 2005 Regulations, which we refer to herein as the "Proposed Regulations." We believe that the comments and recommendations we offer here will substantially improve the Proposed Regulations and better support the ORI/institutional partnership that is vital to promoting research integrity.

MAJOR CONCERNS WITH THE PROPOSED REGULATIONS

Below we describe major areas of concern in the Proposed Regulations. Each section begins by setting forth general comments, followed by comments on specific provisions of the Proposed Regulations relevant to the broader area of concern.

(1) Inappropriate Limitations on Institutional Authority During Pre-Investigative Review Process

The Proposed Regulations impose additional, constraining, and unfair regulatory requirements on how institutions conduct the initial assessment of research misconduct allegations. These requirements run contrary to the roles and responsibilities that Congress established for institutions under the NIH Revitalization Act of 1993¹ (“Revitalization Act”). They also curtail institutions’ ability to consider certain defenses at the inquiry stage, which creates unnecessary burden for institutions. This proposed approach also is fundamentally unfair to respondents because it prevents them from being able to conclude review proceedings at the earliest possible stage. Accordingly, we urge ORI to modify the Proposed Regulations to explicitly permit pre-investigation consideration of all defenses.

Section 93.306 of the Proposed Regulations creates a highly formalized assessment phase of the review process that places severe constraints on institutional authority and decision-making. These constraints do not align with the roles and responsibilities that Congress set forth for institutions in the Revitalization Act. Specifically, Congress required PHS-funded institutions to:

- Assure HHS that the institution has in effect “an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by” the institution; and
- **“Report to the Director [of ORI] any investigation of alleged research misconduct in connection with projects for which funds have been made available under this Act *that appears substantial.*”² [Emphasis added].**

In establishing these responsibilities, Congress recognized that institutions are in the best position to evaluate allegations because they understand the pertinent science and research environment and can directly assess evidence and witnesses. This allocation of duties also mitigates the potential harm to researchers’ reputations that can occur if PHS is notified of an allegation of research misconduct **before** the institution has determined that the allegation is within PHS’ jurisdiction and appears substantial. The 2005 Regulations appropriately implemented the Revitalization Act’s directive by delegating to institutions the primary responsibility for the initial

¹ Pub. L. 103-43, 107 Stat. 122 (Jun. 10, 1993).

² *Id.* at §161 setting forth modifications to §493(b)(1)-(2) of the Public Health Service Act (codified at [42 U.S.C. §289b](#)). *See, also*, [Health Research Extension Act of 1985, Pub. L. 99-158, 99 Stat. 820 \(Nov. 20, 1985\)](#).

assessment of research misconduct allegations and requiring notification of ORI when the institution determines that an allegation meets the criteria at 42 CFR §93.307(a).³

The Proposed Regulations ignore the Revitalization Act's limits by creating a formal assessment phase that inappropriately curtails institutional decision-making autonomy. For example, institutions are limited to the review of "readily accessible information relevant to the allegation"⁴ and must complete the assessment within 30 days.⁵ If institutions exceed this deadline, they must **automatically advance** to inquiry, regardless of the nature of the allegations and associated information and documentation.⁶

Requiring an institution to conduct an inquiry for allegations that were not assessed within 30 days **and** that were not sufficiently credible and specific places completely unnecessary costs and burdens on the institution. This includes the cost, burden, and disruption imposed by sequestering relevant research records, when no inquiry may be warranted. For example, this automatic inquiry would trigger the time-consuming and costly collection and sequestration of lab notebooks, computer hard drives, physical materials, and other relevant research materials, as well as cause severe disruption to ongoing research activities and reputational harm to the individuals whose records are requested. Even more troubling is the negative impact on an individual respondent who would be subject to an inappropriate inquiry purely because of administrative delay that falls outside of the respondent's control.

The Proposed Regulations inappropriately fail to recognize that ORI and institutions conduct **separate research misconduct review processes that are necessarily subject to different standards**. ORI's review process must conform to the stringent federal debarment and suspension regulations⁷ because those actions are possible penalties if ORI makes a finding of research misconduct. Internal institutional processes are not bound to follow the same requirements, but they may need to conform to institutional, and/or state and local requirements. Yet rather than give institutions appropriate discretion in the conduct of their research misconduct review processes, the Proposed Regulations appear to reflect ORI's expectation that an institution conduct a review for ORI that meets the standards that only apply to ORI's review. This approach streamlines ORI's review, at institutions' expense.

The Proposed Regulations also require institutions to develop a formal assessment report to which ORI may have access, even if the allegations are determined not to warrant an inquiry.⁸ This approach expands ORI's authority to encompass allegations that **do not meet** the standard for

³ "An inquiry is warranted if the allegation – (1) Falls within the definition of research misconduct under this part; (2) Is within §93.102; and (3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified."

⁴ Proposed Regulations at §93.205.

⁵ Proposed Regulations at §93.306(e).

⁶ Proposed Regulations at §93.306(e)(2).

⁷ See, [42 CFR Part 93, Subpart D](#) and [2 CFR Part 376](#) (Dept. of Health and Human Services implementation of overarching federal non-procurement debarment and suspension requirements at [2 CFR Part 180](#)).

⁸ Proposed Regulations at §93.306(d).

inquiry, let alone investigation, and thus fall outside the scope of the PHS research misconduct regulations.

Finally, the Proposed Regulations also constrain institutional actions during the inquiry stage of review by prohibiting consideration of the defenses of honest error or difference of opinion at inquiry, even when there is solid information to support their application.⁹ Although the 2005 Regulations do not contain such an explicit prohibition, the preamble to those regulations expressed ORI's view that it is inappropriate for the inquiry report to dismiss allegations based on honest error or difference of opinion.¹⁰ However, neither the preamble to the 2005 Regulations nor the preamble to the 2023 Proposed Regulations offer any statutory or legislative justification for this approach. Indeed, the 2005 preamble states that "a finding that the research misconduct is conducted intentionally, knowingly, or recklessly is necessary for a finding of research misconduct" and that evidence of such defenses may be included in the inquiry report. Yet perplexingly, the 2005 preamble goes on to state in conclusory fashion and without support that:

[I]t would be inappropriate for the inquiry report to conclude, on the basis of an initial review of the evidence of honest error or difference of opinion, that the allegation should be dismissed."¹¹

In short, in both 2005 and 2023, ORI has not provided any justification for requiring an institution to proceed to investigation in cases where there is clear and substantive information at or before inquiry to establish honest error or difference of opinion.

Unnecessarily prolonging the review process in this manner is unfair and burdensome to respondents because it deprives them of the ability to raise, and have defenses considered at the earliest stage possible of the review process. This approach may also have a chilling effect on researchers by inhibiting them from self-identifying errors and delaying correction of the research record. Eliminating honest error and differences of opinion as defenses at the inquiry stage also overburdens institutions by forcing them to conduct investigations into, and report to ORI on, matters that do not constitute research misconduct and that fall outside the scope of the PHS regulations. Further, it disregards the potential damage to researchers' reputations that stems from reporting to ORI (or providing ORI with access to) information on allegations that the institution determines do not warrant investigation. Most importantly, this provision ignores a researcher's right to a presumption that they have not committed research misconduct **and will not be subject to an inquiry and investigation** unless and until it is warranted by the underlying substance of the allegations and supporting information.

Specific Recommendations

To address the foregoing concerns, we urge ORI to make the following modifications to the noted sections of the Proposed Regulations:

⁹ Proposed Regulations at §93.307(f)(2).

¹⁰ [70 F.R. 28370](#), 28378 (May 17, 2005).

¹¹ *Id.*

- **§93.205 Assessment**

ORI should delete this definition for the reasons discussed above. Overall, the Proposed Regulations' creation of a separate assessment phase is inconsistent with the assessment's primary purpose, i.e., determining if the allegations are subject to the regulations in the first place. If ORI retains this definition, it should delete the following sentence, as the remainder of the definition sufficiently limits the scope of the assessment:

The assessment only involves the review of readily accessible information relevant to the allegation.

- **§93.306 Institutional assessment**

As detailed in the previously outlined rationale, ORI should delete this section in its entirety and instead retain the 2005 Regulations' approach to the initial assessment of research misconduct allegations (i.e., a mostly informal process conducted solely by institutions without any formal procedural or reporting requirements). Additional regulation of the assessment process is excessive because the threshold for moving allegations to inquiry is low, and allegations that do not meet this threshold merit no further attention by ORI.

- **§93.307 Institutional Inquiry**

Subsection (a)(1) – ORI should delete this subsection, which requires that any assessment not completed within 30 days automatically move to inquiry regardless of the substance of the allegations. As noted, this approach unfairly punishes the respondent by potentially moving unmeritorious allegations to inquiry merely because the institution failed to meet an arbitrary 30-day deadline, and ORI has not provided any rationale to support this significant change.

Subsection (f)(2) – ORI should delete this subsection which prohibits an institution from making a finding of honest error or difference of opinion at the inquiry stage even when there is adequate evidence to support such finding. As previously discussed, this approach unfairly subjects the respondent to an unwarranted investigation process. It also taxes institutions with the burden of conducting this unnecessary investigation even when the institution may reasonably conclude that the behavior does not fall within the definition of research misconduct.

- **§93.309 Reporting to ORI the decision to initiate an investigation**

Subsection (a)(4) – As written, this subsection contradicts §93.307(e)(2), which states that committees of experts are not required for the conduct of an inquiry. Accordingly, we recommend that this subsection be modified by deleting “composition of the inquiry committee” and replacing it with the phrase “person(s) who conducted the inquiry and/or provided subject matter expertise.”

Subsection (c) – ORI should modify this section to clarify that institutions, not ORI, make the final determination as to whether an inquiry will proceed to investigation. This approach is

consistent with the Revitalization Act and helps to ensure that both ORI and institutions are not overburdened with unnecessary cases.

(2) Transition from Peer-Driven to Prosecution Focused Review Process

The Proposed Regulations transition the review of research misconduct allegations from a peer-driven process focused on ensuring the accuracy of the scientific record to a prosecution-focused, time-line driven process apparently designed to elevate all allegations of research misconduct to the investigation stage as quickly as possible. They also focus on the creation of a detailed and all-encompassing “institutional record,” that is designed to meet a standard that applies to debarment proceedings, thereby unduly complicating the institutional process. This emphasis on documenting the “record” will discourage reporters – including self-reporters – from coming forward with allegations and concerns, and it will create unnecessary administrative burden for institutions. We urge ORI to: (a) abandon the Proposed Regulations’ new concept of prioritizing the institutional record; and (b) increase, rather than decrease, procedural flexibility for institutions, particularly during pre-investigation stages of review, to provide appropriate “off-ramps” for matters that do not warrant moving to investigation.

As set forth in Section 1, the Proposed Regulations constrain institutions’ decision-making autonomy. They also incorporate numerous checkpoints at which ORI may examine and potentially override institutional decisions in on-going proceedings,¹² and preserve, or add new, rigid timelines.¹³ All of these provisions ignore the fact that research misconduct reviews are a fact-driven, peer-driven, scientific processes that do not easily map to an overly prescriptive administrative process. The review process should provide sufficient flexibility for institutions to triage allegations that do not neatly fit within the regulatory definitions, determine how to prioritize the review of multiple different allegations, and ensure appropriate review for the wide variety of research misconduct allegations that arise, taking into account different levels of complexity.

The overall impact of these provisions is to relegate institutions to a more ministerial role that focuses on gathering information for the institutional record¹⁴ and satisfying documentation requirements, such as transcribing all interviews and numbering exhibits, to meet an administrative law standard that applies **only** to ORI’s investigation process.¹⁵ This focus on developing a judicial type “record of the proceeding” significantly harms an institution’s ability to provide a confidential “safe space” in which individuals can feel comfortable bringing forward potential research

¹² See, e.g., §93.105(b)(1)(ii) (ORI must be informed before an institution can determine that the subsequent use exception does not apply); §93.306(d)(3) (ORI may examine an institution’s assessment report, even if the institution does not proceed to inquiry); §93.307(h)(2) (ORI’s permission is required to extend inquiry period).

¹³ Proposed Regulations at §93.307(a)(1) (strict 30-day deadline for assessment); §93.307(h) (60-day deadline to complete inquiry); §93.311(a) (180-day deadline to complete investigation); §93.314 (120-day deadline to complete appeals process).

¹⁴ Proposed Regulations at §93.223.

¹⁵ Proposed Regulations at §93.305(g).

integrity concerns for frank discussion about whether they may constitute allegations of research misconduct encompassed by the PHS research misconduct regulations. Further, this approach risks stigmatizing honest human error in science by discouraging prompt reporting of discrepancies and self-correction because reporters will be understandably concerned that any research integrity-related question or concern they bring forward will be transcribed, fast-tracked to investigation, and reported to ORI.

Finally, we wish to note two specific provisions that inappropriately discount the necessity of ensuring that the review of research misconduct allegations remains peer-driven and considers discipline-specific standards. First, the Proposed Regulations include a requirement that “voting or split decisions by the investigation committee members are not permitted in the final recommendation in the investigation report.”¹⁶ This provision fails to recognize the professional independence of the scientific experts who make up the committee, and even more consequentially, it violates the respondent’s rights to a fair adjudication of the allegations. Second, the Proposed Regulations include a definition of “accepted practices of the relevant research community”¹⁷ that fails to recognize that scientific norms and standards are highly discipline specific and may evolve over time as new technologies are developed and new scientific specialties emerge.

Specific Recommendations

To address the foregoing concerns regarding the Proposed Regulations, COGR strongly recommends that ORI make the following modifications to the noted sections of the Proposed Regulations:

- ***§93.200 Accepted practices of the relevant research community***

As noted, this definition incorrectly assumes the existence of a universal set of professional codes or norms, when, in fact, scientific and professional norms and standards are highly discipline specific. It also incorrectly assumes that all practices established by PHS funding components, which cover a vast range of topics, are related to research misconduct. To address these incorrect assumptions, we urge ORI to amend this definition to state:

Accepted practices of the relevant research community means: (a) the commonly accepted professional norms and/or standards within the relevant discipline-specific research community aimed at ensuring research integrity and preventing fabrication, falsification, and plagiarism; and (b) those practices that are established by the PHS component that funds the research under review specifically aimed at preventing research misconduct and promoting research integrity.

¹⁶ Proposed Regulations at §93.313(l)(2).

¹⁷ Proposed Regulations at §93.200.

- ***§93.223 Institutional record***

ORI should delete this definition and all references to it within the Proposed Regulations. As previously discussed, the Proposed Regulations' "hyper-focus" on documenting the procedural record will dampen reporting and harm institutional efforts to appropriately evaluate and triage allegations at the early phase of the review process. If ORI elects to retain this definition, we recommend that Subsections (a) and (b) be modified as follows:

- Delete the reference to "assessment report" in accordance with our prior recommendations.
- Delete the words "and documents" from subsection (a) and delete subsection (b) in its entirety. In their current form, these subsections require institutions to document their determination that certain records are not relevant to the research misconduct proceedings or are duplicates of other records that the institution retains. Institutions often sequester an enormous number of records during a research misconduct proceeding, and requiring institutions to not only index these records, but also document determinations of irrelevant or duplicative records (which, by definition, are not part of the institutional record) is a wasteful allocation of scarce institutional resources. Accordingly, these requirements place an unwarranted burden on institutions and should be removed.

- ***§93.300 General responsibilities for compliance***

Subsection (g) – This provision contains a broad mandate for institutions to cooperate with ORI, thus making the following text superfluous: "including addressing deficiencies or additional allegations in the institutional record if directed by ORI." We suggest deleting this quoted text. If ORI retains this text, we recommend that this section make clear that an institution may object to an ORI directive if an institution believes the directive to be erroneous or inconsistent with ORI's authority and can provide supporting information to this effect.

- ***§93.305 General conduct of research misconduct proceedings***

Subsection (d) Multiple Respondents – We support this section's requirement for institutions to consider whether there may be additional respondents, but the section's wording should be modified as follows to make clear that individuals should be named as respondents **only** when there is sufficient evidence to support this designation:

- Substitute "may" for "must" in the second sentence and add the following text to the end of this sentence: "if there is sufficient evidence to support such inclusion."

Subsection (g) Interviews – ORI should delete this subsection's requirements that institutions: (a) transcribe interviews conducted during the assessment and inquiry stages of the review process; and (b) number exhibits and refer to these numbers during such interviews. As previously discussed, these requirements will intimidate individuals who bring forward allegations and concerns and adversely impact institutional efforts to encourage reporting. The

proposed requirements are inconsistent with a peer-directed process that in the early stages may involve informal discussions to understand the scope of persons involved in the research and the location of relevant records. Further, they create substantial administrative and cost burdens on institutions. If ORI insists on verbatim records of interviews that take place prior to investigation, we urge ORI to: (1) limit this requirement to interviews of identified respondent(s) and complainant(s) that take place during inquiry, and (2) permit institutions – at their discretion – to provide alternate forms of recording (e.g., audio), in lieu of transcripts. These options provide institutions with a more flexible and lower-cost method for maintaining an accurate record of interviews that is less taxing of scarce institutional resources (particularly for smaller institutions) and less likely to discourage reporting.

- **§93.307 Institutional Inquiry**

Subsection (d) – This subsection requires institutions to “obtain all” evidence. It should be modified to clarify that institutions have an obligation to use reasonable efforts to sequester evidence that is within their custody and control and that has been determined to be reasonably relevant to the matter at hand.

Subsection (h) – ORI should extend the deadline for the conduct of the inquiry to 120 days and delete the requirement that an institution obtain ORI’s approval for an extension. The inquiry process is complicated and requires coordination of the complainant, respondent, and often, scientific experts who serve on the inquiry committee or advise the process. Experience under the 2005 Regulations has shown that 60 days is not enough time to conduct this process. Further, institutions should determine if, and how long, to extend the inquiry period based on the specifics of each case. Requiring ORI’s permission for an extension is inefficient and risks tarnishing a researcher’s reputation prior to a determination that allegations may have substance and are consistent with the scope of ORI legislative authority. If ORI retains the permission provision, it should not require institutions to disclose any identifiable information in the extension request.

- **§93.311 Time limit for completing an investigation**

ORI should extend the deadline for completion of the investigation to 365 days. The investigation process is complicated and requires coordination of the complainant, respondent, and scientific experts who serve on the investigation committee or advise the process, as well as the conduct of detailed document review, formal, transcribed interviews, examination and analysis of all evidence, and the drafting of a carefully documented report. We appreciate the fact that the Proposed Regulations extend the investigation period from 120 to 180 days, but experience under the 2005 Regulations has shown that many investigations require a year or more to complete, and ORI routinely grants extensions in such cases. COGR agrees that institutions should be diligent in carrying out the investigation and would support provisions that require: (a) institutions to provide ORI with periodic status reports on the investigation’s progress after the 180-day mark; and (b) ORI permission to extend an investigation beyond 365 days.

- **§93.313 Investigation Report**

Subsection (l)(2) – For the reasons discussed above, ORI should delete this subsection’s requirement that “voting or split decisions by the investigation committee members are not permitted in the final recommendation in the investigation report.”

- **§93.314 Institutional investigation, institutional appeals**

Institutional appeals are governed by internal processes and, in many cases, state and/or local laws and regulations. Accordingly, institutions may be procedurally or legally prohibited from imposing the 120-day appeal deadline set forth in this section. Accordingly, we recommend that this section be modified to limit ORI’s constraints on internal appeals process to receipt of institutional notification as to the initiation and outcome of the appeal process, along with a description of the appeals process.

(3) Increased Complexity and Confusion

The Proposed Regulations fail to accomplish ORI’s stated goal of reducing the confusion and complexity of the 2005 Regulations. Instead, they create added complexity and confusion, along with attendant administrative burden and costs. We encourage ORI to fully consider our specific recommendations outlined in this section. We believe suggestions will make the Proposed Regulation more understandable and simpler for institutions to implement.

COGR appreciates ORI’s recognition in the NPRM preamble that “the 2005 Final Rule’s complexity and missing definitions create confusion in some areas.”¹⁸ However, the numerous unnecessary, and/or unnecessarily complicated, defined terms coupled with detailed process requirements cause the Proposed Regulations to read like a code of civil procedure, instead of clear and broad guidance about how institutions should conduct a peer-driven review of research misconduct allegations.

Specific Recommendations

Below we offer our comments on the defined terms included in the Proposed Regulations that we have not previously addressed. We also provide suggestions for reducing other overly complicated or confusing provisions of the Proposed Regulations, including those regarding the “subsequent use exception.”¹⁹

- **Unnecessary Definitions**

We appreciate ORI’s inclusion of all defined terms in one subpart. However, we note that the Proposed Regulations include some newly defined terms that are unnecessary because they are either addressed in other sections of the regulations or they pertain to commonly known terms that require no definitions. Accordingly, in addition to our suggestions below concerning

¹⁸ NPRM at p. 69584.

¹⁹ Proposed Regulations at §93.105(b)(1).

defined terms, we recommend that ORI delete the definitions for the following terms: “appeal” - §93.204, “day” - §93.209, and “knowingly” - §93.226.

- **§93.105(b)(1)(i) – (ii) Time Limitations; Exceptions to the six-year limitation, Subsequent use exception**

The proposed changes to this section do not clarify the subsequent use exception, and it remains difficult for institutions to apply. We recommend that ORI abandon the subsequent use exception and establish a firm period of limitations to ensure that respondents are not required to defend against charges for which evidence and witnesses are no longer available. In this respect, we suggest that ORI adopt the 10-year upper limit for claims brought under the False Claims Act.²⁰ This approach will also reduce the need for institutions to engage in time-consuming, and frequently fruitless, searches for such evidence and witnesses.

If ORI retains the subsequent use exception, the Proposed Regulations should be modified to expressly state that the exception: (a) applies only to the respondent’s use or re-publication in the research record of specific data that are alleged to have been fabricated, falsified, or plagiarized; and (b) does not encompass mere citation of a potentially problematic paper in a researcher’s *curriculum vitae*, grant application, biographical sketch, or reference list.

Finally, ORI should delete the provision in subsection (ii) requiring institutions to “inform ORI of the relevant facts before concluding the exception does not apply.” This requirement suggests that ORI does not trust institutions to decide whether the subsequent use exception applies. Rather than adding this extra burden of potential disclosure to ORI before the investigation phase, ORI should focus on drafting the clearest possible regulation and accompanying frequently asked questions concerning application of the subsequent use exception. Accordingly, the current process of allowing institutions to determine when the exception applies should remain in place.

- **§93.203 Allegation**

ORI should make clear that non-specific statements of research misconduct and general on-line public comments do not constitute allegations for the purposes of the Proposed Regulations. We suggest the following alternative definition:

Allegation means a purposeful disclosure of possible research misconduct through any means of communication that specifically alleges wrongdoing encompassed by this part and is brought directly to the attention of an HHS official, an institution’s research integrity officer, or another institutional official whose duties include matters of research integrity. This definition excludes public comments posted online (or in similar public forums) that are not brought to the attention of the foregoing officials.

²⁰ [31 U.S.C. §3731\(b\)](#).

- **§93.207 Complainant**

ORI should modify this definition to make clear that a complainant may act as a witness in a research misconduct proceeding but is not otherwise involved in the institutional process for the review of research misconduct allegations.

- **§93.211 Difference of opinion**

This definition is unnecessary and should be deleted because the scientists who comprise the inquiry and investigation committees are experienced in distinguishing between criticisms that are part of normal scientific exchange/evaluation and allegations that underlying data is not reliable. If this definition is retained, the last sentence of the definition should be revised as follows because it is ***interpretations of*** data that are subject to differing opinions:

The differing opinion must concern scientific methodology, analysis, interpretations, or conclusions, not policy opinions or decisions unrelated to data interpretations.

- **§93.234 Recklessly**

We appreciate ORI's inclusion of a definition of the term "recklessly." We encourage ORI to modify this definition as follows to avoid conflating the definitions of "knowingly" and "recklessly" and to ensure that the term is defined in the context of research misconduct:

Recklessly means that:

- *The respondent, in proposing, performing, or reviewing research, or in reporting research results, was consciously aware of a substantial risk that such conduct could result in falsification, fabrication, or plagiarism; and*
- *In the face of this substantial risk, the respondent, either by action or inaction, failed to do what a researcher of ordinary prudence in the relevant research community would have done under these circumstances to mitigate the risk.*

- **§93.240 Research record**

ORI should make the following modifications to this definition to improve its clarity and ease of implementation:

- Insert the phrase "record of" before the term "oral presentations" because fully oral presentations cannot easily or reliably be reviewed.
- Add text to expressly exclude from the definition any records of completely internal presentations (e.g., lab meeting reports) that are identified and corrected before any outside reporting occurs.
- Delete the phrase "internet and online content," which is unnecessary because the definition already states that data or results may be in physical or electronic form.

(4) Inadequate Confidentiality Protections

Certain provisions of the Proposed Regulations fail to adequately protect the confidentiality of participants in the research misconduct process. We urge ORI to implement our specific recommendations detailed below, which we believe will prevent unnecessary reputational harm to respondents and others, while permitting institutions to quickly address errors in the scientific record.

We are deeply concerned about the potential reputational damage posed to respondents and other individuals by the provisions that permit: (a) “need-to-know” disclosures to third-party institutions regarding respondents for whom an institution has not yet made findings of research misconduct;²¹ and (b) ORI’s publication of institutional research misconduct findings and related institutional actions in cases that ORI has not settled or made its own findings of research misconduct.²² We believe that these sections require substantial modification or deletion, as detailed in our specific recommendations. We also include in this section our comments on the issue of anonymity, per ORI’s request in the NPRM.²³

Specific Recommendations

To address the foregoing concerns regarding confidentiality, we strongly encourage ORI to make the following modifications to the noted sections of the Proposed Regulations.

- ***§93.106 Confidentiality***

Subsection (a) – ORI should modify this subsection to make clear that confidentiality requirements concerning the identities of complainants, respondents, witnesses, and the existence of research misconduct proceedings are limited to the period prior to the point at which a finding of research misconduct is made. This approach affords respondents appropriate reputational protections unless and until findings of research misconduct are made, while allowing institutions to make appropriate disclosures **after** there are findings of research misconduct, unless there is a “need to know” as set forth in the rest of this section.

Subsection (c) – We support the intention of this subsection but urge ORI to clarify that “those who need to know” specifically includes journals, editors, and publishers. This modification can be accomplished by adding the phrase “which may include journals, editors, and publishers” to the end of this subsection.

Subsection (d) – A research record may be unreliable for a host of reasons, most of which do not include research misconduct. The issue of record discrepancies is separate and distinct from the cause of such discrepancies, and thus, the “reliability of the research record” should not be made confidential under the Proposed Regulations. Accordingly, we strongly suggest

²¹ Proposed Regulations at §93.106(e).

²² Proposed Regulations at §93.410(b).

²³ NPRM at p. 69585.

that ORI delete this subsection because it prevents institutions from promptly correcting the research record when they have clear evidence that data are unreliable because of discrepancies that are the subject of a research misconduct proceeding. Institutions should be empowered to facilitate such corrections when there is solid evidence that the research record is unreliable, even though questions of fabrication, falsification, or plagiarism and responsible parties have yet to be determined.

Subsection (e) – ORI should delete this subsection because it permits broad “need-to-know” disclosures to institutions that are not conducting the research misconduct proceeding (“third-party institutions”) **prior** to the point at which an institution makes findings of research misconduct. This approach places a respondent’s reputation, research funding, and employability at risk, without giving the respondent an opportunity to defend themselves, and is thus inconsistent with basic precepts of due process.²⁴ Although we support the intent of subsection (e)(1) to support institutions’ efforts to secure relevant records held by a third-party institution, we note that subsection (a) already empowers institutions to do so. Further, with regard to funding, we note NIH has processes in place to address concerns about situations in which a person alleged to have committed research misconduct seeks to have that funding transferred to a third-party institution. Specifically, NIH “expects both the relinquishing and applicant organizations to disclose whether a Change of Recipient Organization is occurring within the context of an ongoing or recent investigation of misconduct of any kind, including, but not limited to professional misconduct or research misconduct.”²⁵ This process appropriately permits institutions to notify NIH, which makes its own determination regarding funding, without directly involving other institutions.

- ***§93.401 Interaction with other entities and interim actions***

This section describes ORI’s ability to notify and consult with other government and private agencies if those entities “have a need to know about or have information relevant to a research misconduct proceeding,” as well as to refer matters to the U.S. Department of Justice, Department of Health and Human Services Office of the Inspector General, or other federal, state, or local offices involved in investigating or pursuing research misconduct allegations. To enable institutions to properly administer research misconduct proceedings, including the assessment of any breaches of confidentiality, we request that ORI amend this section to include an obligation on ORI’s part to notify the research integrity officer or institutional certifying official of any such notices or referrals by ORI that take place while the research misconduct proceedings are in process at the institution.

- ***§93.410 Final HHS action with no settlement or finding of research misconduct***

Subsection (b) – This subsection permits ORI to “publish notice of institutional research misconduct findings and implemented institutional actions related to the falsified, fabricated,

²⁴ Note that for state institutions, there also may be further state law limitations on reporting internal matters before conclusion.

²⁵ NIH, [NOT-OD-20-124, Guidance Regarding Change in Status, Including Absence of PD/PI and Other Key Personnel Named in the Notice of Award \(Jun. 11, 2020\)](#).

or plagiarized material in the research record, but not the names or other identifying information of the respondent(s), if doing so is within the best interests of HHS to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, or to conserve public funds.” This requirement fails to consider institutional, state, and local privacy and confidentiality requirements. Although it states that names or other identifying information of the respondent will be removed, it fails to consider the impact on reputations of collaborators and co-authors on affected projects or publications against whom there were no findings of research misconduct. It also deprives institutions of the right to request confidential treatment of information provided to the federal government that is outlined in the federal Freedom of Information Act.²⁶ Accordingly, we recommend that this subsection be deleted.

- ***§93.414 Interaction with other entities and interim actions***

Subsection (e) – ORI should add to this subsection a requirement for ORI to notify the relevant institution when ORI decides to close a case without a settlement or finding of research misconduct. This modification will facilitate institutions’ monitoring of research misconduct proceedings that have been referred to ORI, as well as managing confidentiality expectations and institutional communications regarding such proceedings.

Comments Regarding Anonymity: The NPRM notes that the Proposed Regulations do not address the matter of granting anonymity to complainants or witnesses in research misconduct proceedings and seeks “views on maintaining anonymity for complainants or witnesses who request it, including whether to include provisions for such anonymity in the final rule.”²⁷ While we note that anonymity can help encourage reporting and reduce the possibility of retaliation against reporters, we concur with ORI’s assessment that anonymity is frequently governed by institutional, state, or other policies. Thus, we support leaving anonymity out of the Proposed Regulations and instead deferring the topic to institutions to address in accordance with their local requirements.

COMMENTS ON THE NPRM’S SECTIONS ON “SUMMARY OF IMPACTS AND THRESHOLD ANALYSIS” AND “REGULATORY FLEXIBILITY ACT” AND A REQUEST TO INCREASE THE IMPLEMENTATION TIMETABLE FOR THE PROPOSED REGULATIONS

As our comments indicate, the Proposed Regulations will substantially increase – not decrease – the complexity of the research misconduct review process. The Proposed Regulations will also generate additional confusion as to how the regulations should be implemented. Accordingly, we strenuously disagree with the following statement in the NPRM:

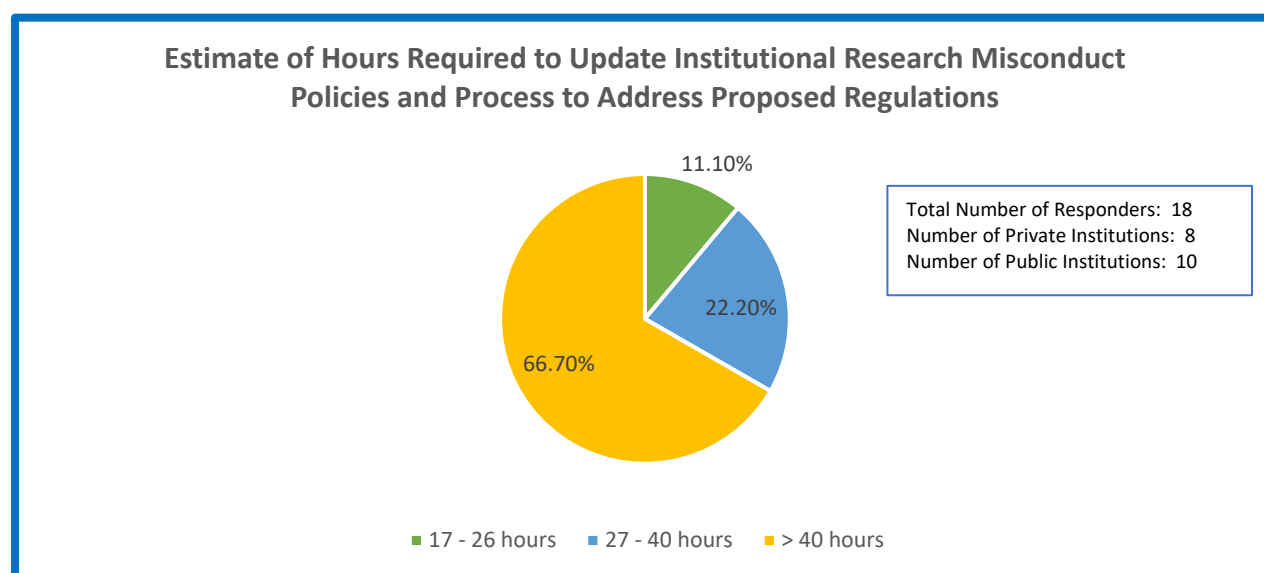
²⁶ See, [5 U.S.C. § 552](#).

²⁷ NPRM at p. 69585.

We anticipate that the proposed rule would likely reduce the burden of compliance by states or other institutions through reduced confusion and uncertainty.²⁸

We also dispute the NPRM's impact assessment estimate that it will take institutions an average of 16 hours to update their policies and procedures for responding to allegations of research misconduct if the Proposed Regulations are adopted. Considering how substantially different the Proposed Regulations are from the 2005 Regulations, this estimate significantly undercounts the time that institutions will spend in this endeavor, particularly when institutional review and approval processes are taken into consideration.

When COGR posed this question to member institutions in a recent survey, 100% of the institutions responded that it would take them more than 16 hours to complete these updates. Although the sample size for the survey was small, the results, as summarized in the chart below, are enlightening.



COGR urges ORI to increase its estimate of the time it will take institutions to update and adopt policies and processes to address the Proposed Regulations and to provide supporting quantitative data for its estimate.

Given the time that it will take institutions to implement the substantial modifications contemplated by the Proposed Regulations, we also urge ORI to reconsider the timeline for implementation specified in the NPRM's preamble. Currently, this timeline anticipates providing institutions no more than six to nine months implementation time, with publication of the final rule in the summer of 2024, and an effective date of January 1, 2025.²⁹ Significant time will be required for institutions to review the final regulations and update their policies and processes. Further,

²⁸ NPRM at p. 69587.

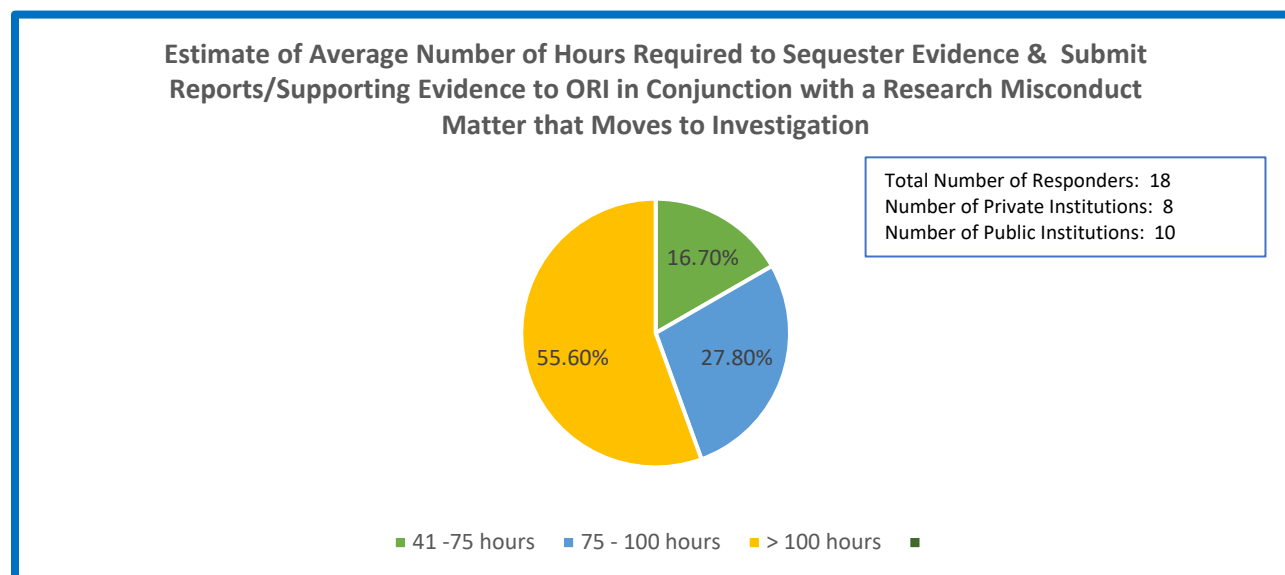
²⁹ NPRM at p. 69584.

many institutions require formalized review by stakeholders for new policies or significant revision of existing policies. In addition to amending their policies and procedures, institutions also will need to revise any training that they have on their processes and communicate the changes to the regulated community. Accordingly, we strongly encourage ORI to afford institutions at least a one-year implementation period after the date on which the final rule is published. Such an extension would be particularly beneficial for smaller institutions with fewer staff and resources.

Finally, we also recommend that ORI consider substantially increasing its estimate of burden on small institutions as set forth in the following statement in the NPRM:

*The most significant burden that could fall on an entity filing a Small Institution Statement is in addressing allegations of research misconduct which would include obtaining all research records and other evidence when there is an allegation of research misconduct, engaging persons to handle the process for addressing the allegations of research misconduct, and submitting reports and evidence to support the small institution's results and conclusions of inquiries or investigations of research misconduct. **The average burden per response is estimated at 40 hours.**³⁰ [Emphasis added.]*

In the same survey described above, COGR asked responders to consider their experience under the 2005 Regulations over the past five years and estimate the average amount of time that it takes for their institution to sequester evidence and submit reports and supporting evidence to ORI in conjunction with a matter that moves to investigation. Once again, as shown in the chart below, 100% of the responders reported that it took them more, and in many cases substantially more, than 40 hours to complete these tasks.



³⁰ NPRM at p. 69588.

Although none of the survey responders meet the Proposed Regulations' extremely narrow definition of a small institution,³¹ an institution's size does not dictate the complexity of the research misconduct allegations with which it may be faced. Accordingly, these results provide insight into the vast number of hours that handling a research misconduct matter requires for all size institutions. COGR strongly recommends that ORI increase this response burden estimate and provide supporting quantitative data for its estimate.

CONCLUSION

ORI had a tremendous opportunity to take the lessons learned from agency and institutional experience under the 2005 Regulations and make substantive improvements to the Proposed Regulations that would benefit ORI, institutions, and participants in research misconduct proceedings. Unfortunately, rather than engaging in an iterative process to learn what changes would be most beneficial to improving these regulations, ORI issued a brief RFI and then proposed modifications that did little to help institutions and participants to streamline processes and rapidly conclude matters. Instead, ORI's Proposed Regulations would: add significant new reporting and administrative requirements with attendant costs; reduce institutional discretion in the conduct of proceedings; restrict mechanisms to terminate a matter prior to investigation; and increase ORI oversight and management of all phases of the review process. While such modifications might be acceptable if they substantially improved research integrity outcomes, we have deep concerns that the suggested revisions will result in numerous negative consequences, including:

- Hampering the reporting of allegations;
- Increasing distrust between the scientific community and administrative and oversight bodies;
- Unfairly damaging a respondent's reputation before allegations are substantiated;
- Eliminating the role of peer review in correction of the scientific record;
- Diminishing a respondent's right to full due process;
- Unnecessarily prolonging reviews that should be terminated at assessment or inquiry; and
- Increasing institutional review, reporting, and administrative burdens and associated costs.

In fact, the only area of the regulation that was streamlined and made less confusing under the Proposed Regulations was the ORI appellate process. And, this streamlining was done at the expense of institutions, due in large part to the newly added extensive requirements for creation and maintenance of the institutional record. This approach unfairly shifts burdens to institutions to generate records that meet a standard that Congress imposed on the agency, not institutions.

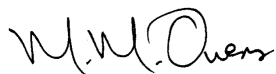
³¹ Proposed Regulations at §93.244 ("A small institution typically has a total of 10 or fewer institutional members.").

Overall, we believe the Proposed Regulations will fail to achieve their stated objective of reducing complexity and alleviating confusion. If institutions were asked whether the administration of research misconduct matters are better and more fairly addressed under the 2005 Regulations, many would unhesitatingly say “yes.” Accordingly, we urge ORI to consider whether implementation of the full slate of Proposed Regulations is the correct path, or whether ORI instead reconsider the 2005 Regulations with an eye toward developing more limited and targeted changes and with the full engagement of the research community.

Should ORI move ahead with the Proposed Regulations, COGR and its member institutions have spent many hours analyzing them and developing recommendations for their improvement. We sincerely hope that ORI will give serious consideration to our suggestions and use them to improve the research misconduct review process for all participants.

Thank you again for the opportunity to submit these comments. Should you have any questions regarding this transmittal please contact me or Kris West, COGR’s Director for Research Ethics and Compliance at kwest@cogr.edu.

Sincerely,

A handwritten signature in black ink that reads "M. M. Owens". The signature is written in a cursive, slightly slanted style.

Matt Owens
President