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Bucking History, ORI Deputy Denies Requests For Misconduct NPRM Comment Extension

By Theresa Defino

In a move that is unprecedented in recent memory, a federal agency has denied a request to extend the comment period on a substantive proposed rule, turning down a plea for 45 more days from stakeholders arguably representing the entire research compliance universe.

At issue is a notice of proposed rulemaking (NPRM) the HHS Office of Research Integrity (ORI) published Oct. 6 with a 60-day comment period that extensively revises HHS' research misconduct regulations for the first time since 2005.[1] ORI oversees compliance and enforcement with regulations governing fabrication, falsification and plagiarism in the billions of dollars of research supported by Public Health Service agencies, including NIH. Its findings of research misconduct are published in the *Federal Register*, with both investigator and institution names included.

Three days after a joint request for more time was sent to ORI Director Sheila Garrity on Oct. 23, Wanda Jones, ORI deputy director, said no.

In Jones' view, the allotted 60 days "is a reasonable comment period under the circumstances," she wrote in an email dated Oct. 26 to the Association of American Medical Colleges, the Association of American Universities, the Association of Public and Land-grant Universities, the Association of Research Integrity Officers (ARIO) and the Council on Governmental Relations (COGR).[2] ARIO posted both the request and Jones' denial on its website.

In seeking the extension, the groups noted that "institutions are deeply committed to ensuring the integrity of federally funded research both proactively, and, when necessary, through the effective and efficient conduct of proceedings to review and consider allegations of possible research misconduct."[3]

Arguing that there will be far-reaching consequences should the proposed rule be enacted as drafted, the groups also noted that the Thanksgiving holiday would shorten the time for comments to be developed.

Time Needed for 'Vital Review'

"The proposed changes to the research misconduct regulations are extensive in number and magnitude, and they will substantially impact our member institutions' policies and processes for handling allegations of research misconduct," the groups wrote to Garrity. "Yet the NPRM affords the regulated community only 60 days to review the changes; compare them with existing requirements; discuss their meaning and impact with researchers, [research integrity officers], and persons responsible for their implementation; and develop and draft comments. Additionally, the Thanksgiving Day holidays will impede the ability to conduct these review activities, thus further curtailing the comment period."

Moreover, the NPRM contains "the first major revisions to the research misconduct regulations that research institutions have seen in 18 years, and they deserve nothing less than a detailed analysis by members of the regulated community," the associations said. "To permit the regulated community to conduct this vital review,

including an analysis of cost impacts, we respectfully request that ORI consider extending the comment period for an additional 45 days that would end on January 19, 2024."

In her email, Jones noted that she, not Garrity, was responding because Garrity "has recused herself from any interactions with ARIO for one year from her resignation from the ARIO Board." Garrity helped found ARIO 10 years ago and was its first president; when Garrity joined ORI in February, she was vice president.

Jones: ORI's Experiences Prompted NPRM

Jones said ORI had signaled it planned to make changes and implied it had heard enough in the lead-up to the NPRM, obviating the need for more time. She noted that ORI had also issued a request for information (RFI) last year.

"Over the years, ORI has heard concerns from stakeholders about 42 C.F.R. Part 93. That stakeholder feedback and ORI's own experience with the 2005 regulation were the impetus for developing and announcing ORI's intent to revise the regulation in spring 2022 via the Unified Regulatory Agenda and Regulatory Plan," she said.

Following the 2022 RFI, published in September of last year with a 60-day comment deadline, ORI heard "further from the public about areas of concern about the 2005 regulation. In drafting the NPRM, ORI carefully reviewed and considered all comments to the RFI as well as the informal stakeholder feedback ORI had received over the years," Jones told the groups in her denial email.

However, the RFI gave no hint as to what ORI might propose and, thus, commenters weren't able to opine on any possible changes the agency itself was contemplating. In fact, in the *Federal Register* post, ORI said it "views this RFI as a brainstorming process. Short responses, limited to just a few words on a given topic, issue, or area will facilitate the organization and categorization of responses. If an idea specifically relates to a part of the current regulation, citing that section (*e.g.*, § 314.3) would be helpful."[4]

Moreover, the NPRM doesn't reflect at least some of the comments ORI received. The agency was asked, for example, to remove "reckless" from the regulation. The word remains and is defined in the new proposed rule.

Before learning Jones' denial was online, *RRC* asked ORI and HHS to comment on the extension request. In initial and follow-up emails, an HHS spokesperson said, "At this time, the Public Comment period is open until December 5th, if we decide to extend, we will let our stakeholders and the general public know." The reply did not acknowledge *RRC*'s questions about the request or address the fact that it had been denied.

"It would have been great to get an extension, especially with the holidays," Kristin West, COGR director of research ethics and compliance, told *RRC.* "We are proceeding to get our response in by the deadline."

Multiple Provisions Spark Concern

Some institutional officials have expressed to *RRC* that many of the proposed changes amount to "regulatory overreach." Other concerns raised are the speed with which ORI seems to be moving toward a final regulation and compliance date and whether institutions could be subject to ORI investigation if they violate any of the provisions that contain the word "must."

Another said some of the changes "will harm reporting and the protection of all parties involved," specifically noting the proposed requirement for "transcripts for all interviews."

Particularly during an initial review to determine whether to proceed to a misconduct inquiry, informal conversations are crucial, and requiring transcripts would have a chilling effect on the gathering of "honest

information," the individual told *RRC.*

Additional proposed changes some see as troubling include a requirement that a finding of "honest error" must be made at the inquiry stage, compared to current practice when this is determined during the assessment stage; the mandate that investigating committees' decisions must be unanimous; and a 30-day limit on the assessment, after which time the institution must inform ORI and request more time.

There are also questions about implementation of proposed "need to know" standards and whether disclosure when there is no finding could prove damaging.

Extension, Delays Common Among Agencies

It is common across the government for comment periods to be extended and even reopened after closure. Similarly, rules often take years to be finalized, partly due to complexity but also because the government wants to include all available stakeholders and not risk being sued, which can result in a rule being thrown out in court.

Many research compliance officials may well remember the path to the revised Common Rule, which began in 2011 with an advance notice of proposed rulemaking (similar to an RFI) and did not conclude until a 2017 final rule. However, implementation dates were delayed several times, with the final compliance date of Jan. 21, 2019.

The Food and Drug Administration's (FDA) NPRM, "Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations," was published Nov. 15, 2018. On Dec. 20, 2018, FDA extended the comment period to Feb. 13, 2019. It reopened the comment period on Feb. 28 of that year, with a new deadline of March 17, 2019.

FDA still has not published a final rule. The most recent entry on reginfo.gov listed last month as an expected publication timeframe, but as of *RRC*'s press time, it had not appeared.

ORI seems to be fast-tracking changes to the misconduct regulations, haste that some stakeholders told *RRC* also raises concerns.

"ORI anticipates release of the final rule in the summer of 2024, with implementation to begin a minimum of 4 months afterward," according to the NPRM. "ORI will aim for an effective date of January 1, 2025," a date it said would "simplify" compliance with institutions' annual reports.[5]

1 Theresa Defino, "'Substantive' Proposed Changes to Misconduct Reg Prompt Calls for Longer Comment Period," *Report on Research Compliance* 20, no. 11 (November 2023), https://bit.ly/3sEeMUs.
2 Wanda Jones, reply letter to request for extension to comment period, October 26, 2023, https://bit.ly/3QCOFFu.
3 Heather Pierce et al., "Request for Extension of Comment Period for Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct," letter to ORI Director Shelia Garrity, October 23, 2023, https://bit.ly/3R4cIyn.
4 Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct, 87 Fed. Reg. 53,750 (Sept. 1, 2022), https://bit.ly/3RZlADB.
5 Public Health Service Policies on Research Misconduct, 88 Fed. Reg. 69,583 (Oct. 6, 2023), https://bit.ly/3tKkiFl.