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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.

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