

Report on Research Compliance Volume 19, Number 10. September 21, 2022 Still Lacking a Permanent Director, ORI Moves To Broadly Revise 2005 Governing Regulations

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Is it OK that the HHS Office of Research Integrity (ORI) hasn't had a permanent director for more than a year or two at a time over the past decade—and has been led by an acting official since the start of the Biden administration?

Is the 12 years of supervision that ORI brokered with a former Einstein College of Medicine investigator for falsifying figures in 16 NIH applications a reasonable punishment—rather than debarment, another option in ORI's sanction bag? And can ORI hire more investigators so it can make more findings?

There's no argument that ORI—which investigates research misconduct in billions of dollars of studies funded by NIH and other Public Health Service (PHS) agencies—has struggled to function in recent years. Wanda Jones, a longtime HHS veteran administrator who has served as acting director numerous times, most recently assumed that title in approximately January 2021; she was named the permanent deputy director in June 2019.

While some of its problems could be addressed by a new director, ORI—under Jones—has instead somewhat puzzlingly started a process that could lead to changes in its governing regulations. It also signaled that it intends to conduct a survey on data management and standard operating procedures (SOPs).

On Sept. 1, ORI published a remarkably broad request for information (RFI) in the *Federal Register* that it likened to the kickoff of a “brain-storming” session to revise its 2005 regulations it says now need to be updated.^[1]

“ORI contemplates beginning a regulatory revision process for the 2005 ORI regulation at 42 CFR part 93 in the near future, using conventional rulemaking processes and channels for public notification and comment,” the RFI states. It is looking for assistance from “individuals, research funding agencies, institutional officials, organizations, institutions, and other members of the general public to help structure ORI's future work toward an updated regulation.”

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