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In Wake of OHRP Director's Complicated Legacy, Calls for Transparency, Resources, Enforcement

By Theresa Defino

At a meeting in mid-December, Julie Kaneshiro, deputy director of the HHS Office for Human Research Protections (OHRP), disclosed the startling news that the agency had 20 staff and 12 vacant positions.^[1]

Now add one more: Jerry Menikoff, M.D., Kaneshiro's boss and OHRP director since 2008, retired at the end of December, a little more than two weeks after Kaneshiro's talk, *RRC* has learned. At the time, Kaneshiro did not mention Menikoff's departure, which concludes a tenure marked by a controversial battle with NIH and a precipitous drop in formal enforcement actions against universities and other institutions conducting human subjects research.

Menikoff also presided over the release of an updated Common Rule, an action that won praise from HHS and a member of an advisory committee that assists OHRP.

With Menikoff's departure, HHS has leadership vacancies in its two research oversight agencies, with no hint as to when new hires will be made. The Office of Research Integrity—which enforces compliance with regulations against fabrication, falsification and plagiarism—has lacked a permanent director since the start of the Biden administration and has been plagued with turnover at the top for a decade or more.^[2]

According to an email provided to *RRC*, Rachel Levine, HHS assistant secretary, announced Menikoff's retirement internally on Dec. 21. "I could not be more proud of Dr. Menikoff and his contributions over the course of his dedicated career," Levine said. "He has been instrumental to the Department and to the nation for the work he has done to protect the rights, welfare, and well-being of subjects involved in research."

Menikoff had a "truly distinguished career serving our nation for more than 15 years, having left his imprint on so many public health initiatives," Levine said in the email. The revised rule "led to regulatory changes that strengthen informed consent and promote the trustworthiness of the research enterprise," she said.

While at OHRP, Menikoff "had a direct impact on providing leadership in the protection of subjects by offering clarification and guidance, developing educational programs and materials, and maintaining regulatory oversight," Levine added.

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