

Report on Research Compliance Volume 21, Number 5. April 25, 2024 OHRP FY 25 Budget Request Lacks Prior Plea For Funding, Staff Increases; Plans Are Modest

By Theresa Defino

In December 2022, Julie Kaneshiro—then deputy director of the HHS Office for Human Research Protections (OHRP)—disclosed that the agency had 32 positions but that only 20 were filled, leaving 12 vacant or “on hold,” due to “resource constraints.”^[1] But OHRP’s budget justification documents for fiscal year (FY) 2025—which begins Oct. 1—propose little additional funding and no new employees. Thus, the situation for this critical oversight agency will not improve anytime soon, and it is likely to continue operating with at least seven fewer staff members than OHRP itself said are necessary.

President Joe Biden submitted the budget request to Congress in March, along with justifications for congressional appropriations committees. These documents are helpful in understanding agencies’ priorities and activities planned for the near future, which in turn can assist compliance officials in developing areas of focus. In the April issue, *RRC* reviewed the administration’s budget requests for the National Science Foundation Office of Inspector General^[2] and the HHS Office of Research Integrity.^[3]

OHRP has oversight of institutional compliance with the Common Rule, designed to ensure the safety of participants in clinical trials supported by NIH and other Public Health Service agencies. But, for more than a decade, as *RRC* has documented, OHRP’s enforcement actions have not only declined but been largely invisible—leading to denouncements from clinical trial watchdogs and ethicists and perhaps giving the impression that those who flout or break the regulations escape both scrutiny and accountability.^[4]

Kaneshiro, who joined OHRP in 2002 and became deputy director in 2014, has been OHRP’s acting director since January 2023, following the retirement of longtime director Jerry Menikoff.

OHRP issues determination letters to institutions indicating whether they have violated the Common Rule or not, and posts these on its website. Investigations by OHRP’s Division of Compliance Oversight (DCO) are usually triggered by complaints, although it also conducts not-for-cause evaluations. Since 2019, in response to the Government Accountability Office’s finding of a lack of transparency about OHRP’s enforcement efforts, DCO has posted quarterly aggregate data on the number of active cases, complaints received and incident reports filed by institutions. These reports address unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with HHS regulations and suspensions or terminations of institutional review board (IRB) approvals.

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