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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.

OHRP's funding in both 2021 and 2022 was $6.225 million. Under the FY 2023 continuing resolution, Congress gave OHRP $6.243 million, an increase of $18,000 for a staff of 24—an increase of four full-time equivalents (FTEs). But OHRP did not fill those slots, Kaneshiro said. Congress appropriated the same amount for this FY, but the agency has still not added staff.

At the time of Kaneshiro's comments, DCO had four FTEs with two positions on hold, according to an organizational chart she shared. OHRP's website still shows four DCO staff.

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Over the last decade, the number of determination letters has dwindled from several dozen per year to zero. In 2021, OHRP issued no letters and just two last year. So far this year, it has issued two.

OHRP also provides educational resources for researchers and other members of the regulated community through its Division of Education and Development (DED). Its Division of Policy and Assurances (DPA) handles federalwide assurances and other tasks. As of December 2022, DED had five FTEs and one position on hold, while DPA had six staff and six positions on hold. Overall, OHRP's website lists 19 staff members by name among the director's office and the three divisions. Presumably, a 20th slot would go to the new director, who has not yet been hired.

Last Year OHRP Sought 28 FTEs in Total

As noted, OHRP isn't requesting much of an increase for the coming FY and is seeking funding to support 21 FTEs —formally enshrining its smaller size. This is in contrast to its prior request, as it made a pitch for more funding and staff for FY 2024.[5] In that request, OHRP sought an increase of $1.486 million above the FY 2023 enacted level, for a total of $7.711 million.

"This level of funding would bring OHRP's staff level to 28 FTEs. At this funding level, OHRP will maintain its current activities supporting the conduct of sound and ethical scientific research, and it will also be able to backfill a total of seven Public Health Advisory…positions," OHRP explained.

Instead, Congress kept OHRP's budget flat in FY 2023 and 2024. No new initiatives are included in the FY 2025 budget request, and few specifics are provided for ongoing activities that will be continued.

Specifically, for FY 2025, the White House is requesting $6.531 million, an increase of $288,000 above the FY 2023 and 2024 amount.[6] "At this funding level, OHRP will maintain its staff level of 21. This includes funding to address inflationary cost increases for the program. At this funding level, OHRP will maintain its current activities supporting the conduct of sound and ethical scientific research," among them educational outreach activities and workshops, the agency said.

Congress could always vote to give an agency more money than it requests, although this is rare.

Regarding its enforcement obligations, the FY 2025 budget request states only that OHRP will "conduct compliance assessments of human research protections programs" and IRBs. The request also states that OHRP expects to "review and process approximately 800-1,000 incident reports, and approximately 400-600 complaints about research."

Complaints Show Drop After Reclassification

DCO's data on its website indicates that most of those complaints won't result in investigations, given that the agency listed a dozen or fewer open investigations per quarter. Moreover, it reclassified complaints in a way that reduces the total. For example, DCO reported receiving 51 complaints in the first quarter of FY 2022, 13 in the second, six in the third and just one in the fourth.

"While the data prior to 2022 includes all complaints received by OHRP, data beginning in 2022 represents the total number of complaints OHRP receives that meet the regulatory definition of human subjects research (HSR) as defined by the Common Rule (45 CFR 46). Most of the complaints received by OHRP pertain to issues that do not involve HSR. Often these complaints are about research that is not covered by the Common Rule or pertain to issues that are not related to research at all," the website states.[7] "Generally, the source of complaints sent to OHRP include, but are not limited to, research subjects and their family members, individuals involved in the

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conduct of research such as investigators and study coordinators, institutional officials, journalists, or media. OHRP takes all complaints seriously."

The most recent DCO data shows OHRP received 19 complaints in the first quarter of FY 2024 and six in the second. In addition, DCO reported 12 open cases—nine for-cause, three not-for-cause—in the first and second quarters.

The budget request also reviewed OHRP accomplishments, which include hosting exploratory workshops and research community forums. It also mentioned supporting the Secretary's Advisory Committee for Human Research Protections (SACHRP), which the agency noted "approved eight sets of recommendations for the Secretary on a range of topics, including the use of artificial intelligence in human subjects research [and] the FDA's [Food and Drug Administration] draft guidance on decentralized clinical trials."

SACHRP recently forwarded recommendations, "Interpretation of the Best Interests Standard for the Retention of Subjects in Human Subjects Research that Has Been Suspended or Terminated," to HHS.[8]

Without providing any details, the agency noted it "opened two cases and closed two cases." It also "processed over 1700 incident reports from institutions engaged in or overseeing HHS-funded human subjects research, and processed over 1000 complaints about research. OHRP also published a new OHRP compliance video to aid institutions in preparation for OHRP compliance assessments."

OHRP Pledges Draft of Rule on 'Burdens'

Looking forward, OHRP plans to undertake the following activities in the upcoming FY, as described in the budget documents:

- "Develop guidance on the revised Common Rule. Priorities for this budget request include incorporating advisory committee recommendations on the ethical principle of justice into guidance and education efforts, continuing active harmonization efforts with FDA counterparts, and identifying gaps in policy and guidance to support trends in the field toward decentralization of clinical research.
- "Pursue rulemaking to address technical issues with the regulations that have resulted in unintended burden on the regulated community.
- "Support OHRP's ongoing role in managing and improving the processes and tools by which institutions register IRBs and obtain assurances to conduct HHS-supported human subjects research."
- "Support OHRP's education team to ensure a steady output of online educational tools and resources that support the work of HHS offices and the general research community for a program of ethical and regulatory oversight of human research protections, maintain current outreach efforts through our Research Community Forums, Exploratory Workshops, and thematic educational workshops, and keep an engaging web presence to promote public trust on research and research participation."

1 Theresa Defino, "With Greater Than Half Its Positions Vacant, OHRP Employing More Technology, 'Creative' Spending," *Report on Research Compliance* 20, no. 1 (January 2023), https://bit.ly/47JYIzz.
2 Theresa Defino, "OIG's FY25 Budget Targets Awardee Compliance With Teaching Mandate, New NSF Initiatives," *Report on Research Compliance* 21, no. 4 (April 2024), https://bit.ly/4cV6sC2.
3 Theresa Defino, "ORI Budget Grew to $15M; HHS Seeks Level Funding to Roll Out Contested Reg," *Report on Research Compliance* 21, no. 4 (April 2024), https://bit.ly/3JpE8tX.
4 Theresa Defino, "In Wake of In Wake of OHRP Director's Complicated Legacy, Calls for Transparency,

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Resources, Enforcement," *Report on Research Compliance* 21, no. 2 (February 2023), https://bit.ly/3W5uWm3.
5 U.S. Department of Health and Human Services, *Fiscal Year 2024 Justification of Estimates for Appropriations Committees*, accessed April 22, 2024, https://bit.ly/3x76Nkw.
6 U.S. Department of Health and Human Services, *Fiscal Year 2025 Justification of Estimates for Appropriations Committees*, accessed April 22, 2024, https://bit.ly/4adjx01.
7 U.S. Department of Health and Human Services Office for Human Research Protections, "DCO Activity Data," content last reviewed April 5, 2024, https://bit.ly/3QcGyA4.
8 Theresa Defino, "SACHRP: With Careful Review, Research Procedures May Continue After Trial Halt," *Report on Research Compliance* 21, no. 5 (May 2024).

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