

# Report on Research Compliance Volume 21, Number 4. March 21, 2024

## ORI Budget Grew to \$15M; HHS Seeks Level Funding to Roll Out Contested Reg

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By Theresa Defino

The HHS Office of Research Integrity (ORI) isn't technically seeking a funding boost in the upcoming fiscal year (FY)—it just wants appropriations equal to this FY in which it got a \$3 million bump courtesy of NIH.

ORI, an agency within the HHS Office of Assistant Secretary for Health, is responsible for investigating incidents of fabrication, falsification and plagiarism within NIH and other Public Health Service agencies and imposing sanctions ranging from supervision to debarment. For two decades, it struggled with high-level dysfunction and vacancies, staff defections over leadership issues and falling numbers of cases that result in findings. Sheila Garrity, who just passed one year in the job, is its fourth director in 10 years.

Last month, President Joe Biden released his proposed FY 2025 budget, along with justifications to Congress that are worth reviewing because they recap prior year accomplishments and establish goals for the upcoming FY. In addition to ORI, RRC reviewed the FY 2025 budgets request for the National Science Foundation (NSF) Office of Inspector General (OIG).

Generally, Congress doesn't enact appropriations that exactly mirror the White House's requests; however, it may come close, particularly when essentially flat funding levels are requested (unless the agency has partisan opponents and is targeted for elimination).

As ORI's FY 2024 budget justification document explained, the request at that time was "\$14,986,000, which is an increase of +\$3,000,000 above FY 2023 Enacted [level]. The FY 2024 request is the amount agreed to by NIH to transfer to ORI for operational costs," the agency said last year.<sup>[1]</sup>

According to the new proposed budget, ORI received \$14.986 million for this fiscal year. Looking to next year, ORI is again seeking this amount, but it doesn't mention any expected contribution from NIH.

If ORI's FY 2025 funding matches FY 2024, the agency's budget will remain \$6.428 million above what it was in FY 2020, reflecting a 75% increase since that year. In both FY 2021 and FY 2022, ORI received \$8.986 million; in FY 2023, funding grew by \$3 million to \$11.986 million.

### **ORI Funding 'Clearly Not Enough'**

Yet, this amount—despite the exponential growth—is simply not enough, argued Ivan Oransky, cofounder of *Retraction Watch*, which monitors research misconduct and the attendant retractions of studies that occur.

Oransky told RRC ORI needs more funding and more authority, positions he has repeatedly argued in published pieces online and elsewhere. In addition to writing and other duties for *Retraction Watch*, Oransky is editor-in-chief of *The Transmitter* and a distinguished journalist in residence at New York University's Arthur Carter Journalism Institute.

Fifteen million dollars "to oversee investigations into how a \$48 billion (and counting) budget is spent is clearly

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not enough,” he told RRC. “Perhaps it should be the equivalent of 2% of that budget since that seems to be how many scientists admit to committing misconduct. But \$1 billion would be dead in the water” because universities would oppose it, he said. “So how about getting it to 0.1% of the equivalent of the NIH budget, or about \$50 million?”

In addition to increased funding, Oransky recommended Congress should give ORI the subpoena power it lacks that the NSF OIG, which investigates misconduct by that agency’s staff and awardees, has. He also recommended moving ORI over to HHS’ OIG to be a separate budget unit, given that OIG “has more power” than ORI.

The FY proposed budget does not contain any such requests to Congress or organizational changes.

Budget proposals are written months in advance and thus are a snapshot in time. As of when ORI’s was completed, the agency anticipated needing additional staff to implement a final misconduct regulation this summer.

However, that timeline seems likely to shift into the future, given the widespread opposition the proposed rule published in October generated. A number of institutions suggested substantive changes; the University of Pennsylvania said it should be withdrawn and a new draft issued.<sup>[2]</sup>

Still, ORI’s budget documents presume a summer final rule, with implementation in FY 2025. “Delaying these changes would continue to burden institutions (and ORI) with an overly complex regulation that had not envisioned the digital revolution (in data, imagery, and analysis, let alone records retrieval and management) of the past 20 years,” agency officials said.

ORI also needs to remain at its current funding level to “expand ORI positions and contracts related to case handling” and what it called “new supportive educational and guidance materials,” according to the budget.

The number of full-time equivalent (FTE) workers at ORI grew from 30 in FY 2023 to 37 this FY, with a total of 42 shown for FY 2025—an increase of five FTEs despite what would be flat funding.

## **Continued AI Investments Cited**

Regarding current and upcoming initiatives, ORI said investments in its “end-to-end assurance and compliance efforts as ORI’s revised regulation takes effect will help protect the public’s investment in biomedical research.”

The agency said that, in FY 2023, it invested in information technology (IT) infrastructure to “support the transfer of its AI [artificial intelligence]-based image analysis tool to the HHS IT environment. ORI will use the balance of its [non-recurrence expense fund] funding in FY 2024 to sustain the AI project. Sustained FY 2025 funding will ensure maintenance of a fully functional, robust, cloud-based database and other IT infrastructure that should improve efficiency of all of ORI’s functions.”

Once testing is completed and the tool is finalized, “ORI anticipates full implementation by FY 2025.”

During this FY, ORI “will begin to roll out” the “critical enhancements to its aging database systems” it began in FY 2022.

“Planned improvements under a new contract include more efficient file access and records management, as well as enhancements to ORI’s assurance database,” the budget states. “ORI envisions a cloud-based system with new capabilities that support and facilitate case handling from intake through disposition, as well as systematic review of institutional policies for handling allegations of research misconduct. Many of these tasks must be conducted manually in the current databases.”

ORI makes limited awards for the development of training and to help sponsor meetings, but the amounts have declined in recent years, and no increase is requested for FY 2025. According to the budget, in FY 2023, ORI issued two new and three continuing awards, ranging from \$49,715 to \$150,000; \$99,331 was the average amount.

However, ORI planned to issue four new awards each in FY 2024 and 2025, but the average amount is expected to be \$50,000. The range of awards is \$25,000 to \$50,000.

## **Budget Reviews FY 2023 Activities**

ORI's list of accomplishments included in the proposed budget refers to FY 2023, which ended Sept. 30. During this period, ORI closed 79 cases, compared to 77 in FY 2022.<sup>[3]</sup>

In FY 2023, ORI also:

- Responded to 336 allegations of research misconduct “through coordination with their respective institutions as needed.” ORI is not clear on whether the coordination is with the complainant’s or alleged perpetrator’s institution. In FY 2022, that number was 267.
- Provided technical assistance to institutions “in over 885 instances,” a decrease from more than 700 reported last FY but an eight-fold increase since 2018.
- Made 11 findings of misconduct, debarring six investigators. In FY 2022, ORI made nine findings, of which two included debarments.
- Issued 10 compliance letters to institutions for failing to maintain an active assurance. ORI’s FY 2024 proposed budget does not mention taking such actions in FY 2023, but states that in FY 2022, “ORI issued a letter of reprimand to an institution that failed to adhere to the federal regulations in its reporting obligations to ORI.” The name of the institution is not included.
- Sponsored two in-person boot camp training sessions for research integrity officers. It also started “an overhaul of the end-to-end boot camp co-sponsorship process, to clarify ORI and institutional roles, allow institutions more discretion in structuring the curriculum and selection of expert faculty, and explore ways to offer the didactic components through short online modules or other means. The overall goal is to reach more institutional research integrity officers whose needs range from just-in-time refreshers to in-depth training.”

<sup>1</sup> U.S. Department of Health and Human Services, *Fiscal Year 2025 Justification of Estimates for Appropriations Committees*, <https://bit.ly/4adjxo1>.

<sup>2</sup> Theresa Defino, “Penn Calls for Withdrawal of ORI’s Proposed Reg; Many Commenters Also Critical,” *Report on Research Compliance* 21, no. 3 (March 2024), <https://bit.ly/3IB2bWC>.

<sup>3</sup> U.S. Department of Health and Human Services, *Fiscal Year 2024 Justification of Estimates for Appropriations Committees*, <https://bit.ly/3x76Nkw>.