

## Report on Research Compliance Volume 22, Number 6. May 22, 2025 Rising Above Fear, Rutgers HRPP Trainer Rallies for OHRP Crippled by Staff Losses

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By Theresa Defino

Michelle Watkinson, institutional review board (IRB) training and communications manager for Rutgers University's human research protection program (HRPP), isn't usually much of a social media user; she left Facebook in 2016. But when she learned in April that Molly Klote, director of the HHS Office for Human Research Protections (OHRP), was let go just six months into the job as part of the government's mass layoffs and that its advisory committee had been dissolved, she was "irked. And that's an understatement."

Watkinson turned to LinkedIn, creating and posting an infographic under the title "A Critical Moment for Research Ethics in the U.S.," in which she decried the terminations and called this a "moment to reaffirm our shared responsibility: to champion ethical, inclusive, and participant-centered research—especially when the systems meant to protect those values are being dismantled."<sup>[1]</sup> That post garnered 332 reactions, 20 comments, 120 reposts and 75 new followers, a response that left her "genuinely humbled and gratified," she said. "I think it's vital to amplify our collective voice."

Since then, she's posted about OHRP approximately six more times and is pondering new ways to keep alive the message of support for the agency, including "potentially establish[ing] collaborative groups dedicated to advocating and advancing" ethical research and to safeguarding programs under attack.

Watkinson, who posts in the evenings and on weekends when she is not at work, was moved to act especially because she had just completed her recertification as an IRB professional through Public Responsibility in Medicine and Research (PRIM&R). She felt a duty not only to raise awareness "but also to encourage many of my colleagues who might feel somewhat helpless but concerned."

She has the support of Rutgers HRPP leadership and obtained permission to speak to *RRC* at a time when many individuals request anonymity for fear of reprisal.

"Speaking up comes with both personal and professional risks. I've thought twice about posting on LinkedIn. I'm still a member of the Rutgers community. I was concerned, but also as a Jewish, disabled woman, I carry with me the story of my family's own Polish and Ukrainian journey to this country to escape genocide. That's been rooted in the pursuit of freedom and dignity. And that's the history that grounds me," Watkinson, who has "very aggressive" Crohn's disease, postural orthostatic tachycardia syndrome and chronic migraines, told *RRC*.

"I understand the fear that comes with advocacy, especially now," she said, noting that her previous advocacy efforts, albeit on a smaller scale, have involved disability justice issues. "I do worry about what it means to speak out in an environment where freedom of speech is increasingly under threat, and where public funding is being weaponized to suppress and defund entire areas of research. We're seeing targeted attacks on work that supports diversity, equity, inclusion, accessibility—DEIA—as well as researching critical public health issues like HIV, black maternal health disparities, LGBTQIA health."

Her "ultimate intention now is to maintain the focus on these critical issues. It's not about myself. It's all about the connection with the peers in our community, but also building, hopefully, a broader network," Watkinson said.

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“You can’t always just remain silent.”

When asked how research funding at Rutgers has been affected since the start of the Trump administration, Watkinson said she had no specific information but pointed to recent aggregate data by the Association of American Medical Colleges and to a public website, <https://grant-watch.us>, which shows that Rutgers lost seven NIH grants (one was reinstated) and eight National Science Foundation awards. On May 13, Sen. Bernie Sanders, I-Vt, issued a report that found “Trump officials effectively cut \$2.7 billion” in NIH funds from January to the end of March, based on a comparison to the first three months of 2024.<sup>[2]</sup>

## **A Reliance on OHRP Leadership**

“This is not just about loss of money, waste of taxpayer money that’s been allocated for different types of research. But it’s human. Participants give their time, they give their hopes, their dreams for a better life, to resolving health conditions of people that they love, for themselves,” Watkinson said. The terminations and weakened condition of OHRP violate participants’ trust in health care and scientific institutions, she added, particularly at a time when officials say they want to restore it. Watkinson is a research participant herself, enrolled in NIH’s All of Us Research Program.

RRC was first to report Klote’s termination and the dissolution of the Secretary’s Advisory Committee on Human Research Protections (SACHRP), which was under OHRP but technically reported to the Office of the Assistant Secretary for Health.<sup>[3]</sup> Most recently, RRC detailed that, due to Klote’s termination, the loss of probationary employees, resignations, retirements and a hiring freeze, OHRP had dropped to nine employees; to be fully staffed, it should have 40.<sup>[4]</sup>

Among those to recently retire is Julie Kaneshiro, formerly OHRP’s deputy director and an agency employee since 2002. Kaneshiro spoke exclusively to RRC about why she felt she had to retire and her hopes for the rebuilding of OHRP. She also called for advocacy of the type in which Watkinson is engaged.<sup>[5]</sup>

OHRP has oversight of some 2,300 IRBs, investigating complaints of noncompliance with the Common Rule and processing incident reports, which cover unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with HHS regulations and suspensions or terminations of IRB approval.

Those in the HRPP and IRB community “rely on [OHRP’s] leadership. Many of us will call them or attend different seminars and ask questions to clarify and interpret regulations, seek out support [for] compliance and to maintain consistent standards nationwide,” Watkinson said. “They have a proactive role in guidance and resources that significantly impact, for example, my daily responsibilities in facilitating education and training to ensure awareness, compliance, regulatory adherence and ethical integrity within my own institution and within our research community.” She also acknowledged that PRIM&R and other organizations have publicly supported OHRP.

## **Help Was Always Available**

Watkinson has had numerous positive experiences with OHRP staff, and she appreciates the office keenly in her professional life.

With degrees in psychology, Watkinson began her career in research compliance in 2004 when she was working at a medical IRB. When she joined Rutgers in 2007 as an IRB administrator, her duties, for the first time, included managing Rutgers’ federalwide assurance (FWA), which was her first exposure to OHRP.

At the time, OHRP’s portal was “very clunky and outdated,” and the FWA process was “all brand new to me.” She added that “speaking directly with the feds intimidated me. I was not as comfortable in speaking up and speaking

out.” But when she contacted OHRP, she found the staff to be “deeply knowledgeable and approachable. The direct contact really humanized the process.”

Later, at Watkinson’s invitation, Elyse Summers, then the director of the Division of Education and Development, and Kristina Borrer, at the time OHRP’s director of the Division of Compliance Oversight, both traveled to Rutgers to provide training; Borrer’s event was open to IRB officials at universities in New Jersey.

In September 2014, OHRP conducted a not-for-cause evaluation of Rutgers HRPP; the agency made one recommendation related to better categorizing IRB meeting minutes but otherwise praised Rutgers, which at the time had nine IRBs and a year earlier had merged with the University of Medicine and Dentistry of New Jersey. This process “deepened my respect for the agency and its mission,” Watkinson said.

This merger involved a “massive undertaking” to combine “three different IRB offices and each one had their own set of boards and committee members,” she said. This required “figuring out how to manage hundreds of people in an effective, efficient manner,” and she again turned to OHRP for assistance. Watkinson had a one-hour Zoom call with Natalie Klein, who was serving at the time as the director of the Division of Policy and Assurances (she is now doing quadruple duty as the acting OHRP director and the acting director of its other two divisions).

Although she hasn’t needed help recently, Watkinson is fearful that such assistance won’t be available to her and others and just knowing there are so few staff will have a chilling effect on individuals contacting the office with questions. Of course, others at Rutgers—and any institution with an FWA—may have pressing needs regarding possible noncompliance and need to reach someone at OHRP right away.

Watkinson has remained in touch with OHRP staff, heard them speak at PRIM&R and agency events and in April 2024, attended OHRP’s two-day research community forum at the University of Florida. OHRP used to hold such forums several times a year; it sponsored this year’s first forum in February with the University of Georgia, but agency staff were not permitted to attend.

## **‘Advocacy Takes Courage’**

She called the appointment of Klote—who spent 35 years at other parts of the federal government, including most recently as the deputy chief research officer for the Veterans Health Administration—“crucial in rebuilding a dedicated, skilled team at OHRP, effectively supporting IRBs, safeguarding rights and welfare of the participants in the research, but also progressively seeking out ways to lead the office forward.”

She worries that OHRP will not be capable of providing guidance and oversight related to crucial issues like artificial intelligence, research involving possible future pandemics and other emerging concerns—issues that historically were tackled by SACHRP. Watkinson said Rutgers staff would watch webcasts of its meetings and stressed the importance of its “thorough” recommendations and the support the panel provided to OHRP. RRC will detail the work of SACHRP and the void its dissolution will leave in a forthcoming article.

The current situation means “there’s an increased risk of inconsistencies in our field, in ethical oversight, [a] weakening of public trust [and] potential harm to research participants,” she said. “My advocacy emphasizes the critical importance of adequately funding and staffing OHRP and demanding the reinstatement of SACHRP to safeguard participant welfare and uphold scientific integrity and foster public confidence in the research enterprise. I’ve been wanting to see that this is taken seriously amongst my colleagues, and I think it definitely has.” For those who want to join her, the best way to contact her is through LinkedIn, Watkinson said.

“I keep a printed copy of the poem, ‘First They Came,’ by my kitchen sink. And every time that I have a privilege to make a meal or to pause and daydream, it serves as a quiet, powerful reminder about the cost of silence and inaction in the face of injustice,” she told RRC. “And advocacy takes courage, and silence carries its own consequences. In

2025, here I am, doing what I can, hoping that [it] empowers others to speak up and encouraging them to find strength in our community, our broad community of research professionals and researchers and members of the community that may benefit from the actual work that's being suppressed."

1 Michelle Wilkinson, "A Critical Moment for Research Ethics in the U.S.," LinkedIn, April 3, 2025, accessed May 19, 2025, <https://bit.ly/43zjbYn>.

2 Theresa Defino, "Is it \$13.5B or \$1.81B? Tallies From 'Trump's War on Science' Differ," *Report on Research Compliance* 22, no. 6 (June 2025).

3 Theresa Defino, "HHS Terminations Include OHRP Director; SACHRP Folded," RRC E-Alerts, April 3, 2025, <https://bit.ly/44IZUF1>.

4 Theresa Defino, "And Then There Were Nine: Disappearing OHRP To Join Enforcement Agency; NIH Cuts Outlined," *Report on Research Compliance* 22, no. 5 (May 2025), <https://bit.ly/4dlWlqo>.

5 Theresa Defino, "'I Really Wanted to Stay': Amid Success, Regrets, OHRP's Kaneshiro Hopes Agency Will be Rebuilt," *Report on Research Compliance* 22, no. 6 (June 2025).