



PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

PRIM&R reached out to thousands of research oversight professionals throughout the United States asking for their thoughts about how recent federal policy shifts and cuts to Department of Health and Human Services (HHS) have affected them.

We received hundreds of replies. Below is a selection of quotations, all of which have been kept anonymous.

*“As the OHRP and SACHRP have been gutted, and funding for research has been cut and will be further reduced (including likely indirect costs reductions), **IRBs and other institutional oversight entities mandated by Federal Regulations to safeguard the rights and well-being of research participants is suffering direct harms** (withdrawn funding, leading to closed clinical trials, lost jobs) and indirect harm to the morale of Institutional researchers, support staff, and other research-adjacent personnel, who now are fearful of the future of research in academic health centers.”*

Human Subjects Research Compliance Monitoring Program; Baltimore, Maryland

“...In research oversight, we are often invisible to the broader scientific enterprise, but our work is essential to ensuring ethical standards, participant safety, and regulatory compliance. In recent months, we've experienced hiring freezes and reduced operational budgets that have affected our ability to efficiently review and monitor protocols. Our IRB staff are carrying higher workloads with fewer resources, which increases the risk of delays and burnout.

We're being asked to do more with less—review more studies, provide more guidance to researchers, and implement complex regulatory changes—without additional support or investment. These pressures not only slow down critical research but also threaten the quality and thoroughness of our oversight.... .

My message to lawmakers is simple: research oversight is not red tape—it's the framework that ensures scientific integrity, protects human participants, and fosters public trust. Undermining the infrastructure that supports ethical research doesn't just affect institutions—it affects every person whose data, time, or health is part of a study. If we want innovation, we must fund and support the systems that make responsible research possible.”

Human Subjects Research, Associate Director; New York, New York



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“Changes to indirect costs initially caused many jobs in the research compliance areas of employment to immediately disappear.... Contractors working on important work at the Naval Medical Research center have been laid off. Contractors at Dept of Homeland Security Science & Technology are facing deep cuts and reorganization of their program, with PIs unsure of what their funding will be in the future, including research on biothreats and emerging pathogens. At the DoD Defense Health Agency, the Congressionally Directed Medical Research Programs have had their funding cut from 1.5 billion to 650 million. Their work usually involves important cancer research, combat casualty care, veteran healthcare research, vaccine development for potential future military deployments, etc.

Although the effects are not immediate now, **we are ceding scientific discovery to foreign nations while at the same time reducing future care for military members and veterans**, as well as the trickle down effects of improving the overall health of U.S. citizens. As our office faces early retirement, deferred resignation, or other staffing shortages, the DHA informed us that the positions will be completely removed from the organizational chart. **Over time, this will slow down important research innovation and overall will make the military less effective and the US less healthy.”**

Regulatory compliance coordinator/officer at a government agency; Frederick, Maryland

“I am a researcher working in a temporary status at a research-heavy state university, where my position is contingent on federal funding. The PI's I work with applied for two NIH grants in October, which were slated to be reviewed in March and possibly funded in July. In January, the review panels were cancelled, and two weeks ago we learned that both of our applications were removed from the review pile, because they were considered to be affiliated with DEI. At the moment, there is a lot of uncertainty about other grants we applied for as well. As a result, my position will be terminated in a month or two, when the existing funding runs out. ... I want the lawmakers to understand that the damages that they are doing right now to the field will be very difficult to reverse, when highly educated people with specific fields of expertise are being forced out.”

Researcher, Human Subjects Research, at an academic institution

“My greatest fear is that U.S. leadership in life-changing research will be thrown away needlessly—a real catastrophe for our nation and the world.”

Human Subjects Research, who serves as a HRPP/IRB/REC Director/Manager



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“SACHRP served our community as a bridge between human research regulations built on foundational ethical principles and research in action. The committee provided thoughtful and practical guidance to questions posed by OHRP, actively interpreting the regulations and applying ethical principles to new and emerging challenges in research (like research using or developing AI, decentralized trials, broad data sharing, genomics, etc.).

The loss of SACHRP - which cost the government almost nothing due to its volunteer structure - means the loss of a crucial ethical compass: We have effectively lost a living mechanism for ethical evolution in research protections. The simultaneous hollowing out of OHRP leaves human research protections functionally adrift. OHRP plays an essential role, not just in regulatory enforcement, but in supporting a culture of compliance, trust, and ethical vigilance.

Without an infrastructure to educate the research community on their ethical responsibility (the why behind the regulations), the research landscape is in danger of fragmenting further, making it vulnerable to egregious lapses in the very protections 45 CFR 46 was drafted to ensure. **From a practical perspective, human research protection professionals who are legally and ethically obligated to report noncompliance and unanticipated problems to OHRP (and other federal agencies who are likewise being gutted) will be left without a functional federal partner to process reportable events, offer guidance and feedback, or take disciplinary action.** The current federal actions have profound ripple effects on scientific discovery and long-term impacts on the health of our nation. The dismantling of our federal partners threatens to reverse decades of progress in human subjects protections, chill important but ethically complex research, and widen the gap between science and the public it aims to serve.

The federal regulations administered by OHRP exist because history has shown us that the pursuit of science alone cannot safeguard human dignity. Without swift and decisive action by Congress to restore expert ethical oversight through a body like SACHRP, and without a fully staffed and empowered OHRP, we risk sliding backwards into a **pre-Belmont era – an era marked by the exploitation of vulnerable populations and the erosion of public trust.**

We simply cannot allow the decades of hard-won progress in human research protections to be undone. Ethics and a commitment to human dignity must take the wheel now, before irreversible harm is done.”

Human Subjects Research Ethicist; New York, New York