

April 3, 2025

Sec. Robert F. Kennedy, Jr.
The U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: The Office for Human Research Protections (OHRP): A Critical Partner for Public Safety and Trustworthy Research

Dear Secretary Kennedy:

We are writing to share our concerns about recent reductions in the Office for Human Research Protections (OHRP) and its capacity to oversee federally funded research. As our joint statement makes clear, without strong support for OHRP, its mission, and its expert staff, there will be a void in the research ecosystem that could lead to significant lapses in research oversight. This void could result in participant harm and loss of the public trust critical to advancing biomedical science, which regulators and the research community have been working to build for over 50 years.

Please find the April 3, 2025 joint statement below from the Association for the Accreditation of Human Research Protection Programs (AAHRPP); the Consortium to Advance Effective Research Ethics Oversight (AEREO); Consortium for Applied Research Ethics Quality (CARE-Q); and Public Responsibility in Medicine & Research (PRIM&R).

The Office for Human Research Protections (OHRP): A Critical Partner for Public Safety and Trustworthy Research

Most Americans have never heard of the US Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP). Yet, OHRP is vital to protecting the rights and welfare of individuals participating in a wide range of research studies designed to advance science and medicine. We urge the Administration to protect and restore OHRP against the loss of expert leadership and to provide the resources necessary to ensure public safety and a trustworthy human research enterprise.

OHRP serves an essential research oversight function, protecting human research participants in a manner similar to how the Federal Aviation Administration (FAA) protects airline passengers. OHRP is uniquely positioned to fulfill its mission to “protect the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the [HHS]... by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.” Historically, OHRP has actively engaged with the public and research community to advance trustworthy science.

To promote efficiency and accountability in both government activity and government-sponsored research, OHRP must have the experienced leadership, resources, and expertise necessary to:

- *Ensure that institutions (and their investigators) receiving federal grant funds are appropriately protecting research subjects, through regulation, guidance, and enforcement;*

- *Reduce unnecessary bureaucracy inhibiting important research, while maintaining the highest standards of participant protection, including meaningful informed consent; and*
- *Promote flexibility in a continuously evolving research environment.*

Without strong support for OHRP, its mission, and its expert staff, there will be a void in the research ecosystem that could be catastrophic. It could lead to significant lapses in research oversight, resulting in participant harm and loss of the public trust critical to advancing biomedical science, which regulators and the research community have been working to build for over 50 years. Furthermore, without the ability to rely on OHRP, institutions may take conservative approaches to research oversight and the pursuit of research, ultimately leaving the American people with fewer innovative treatments and less scientific advancement.

For these reasons and more, we are concerned by recently reported changes in OHRP leadership and the Office's ongoing capacity to oversee federally funded research. We urge the Administration to provide OHRP with both stability and adequate resources to support and continue its important mission.

Thank you for your prompt consideration on this matter.

Sincerely,

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