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Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)
Office of the Director
National Institutes of Health (NIH)

Submitted to DPCPSIreorgcomments@nih.gov

Dear NIH officials,

We commend the establishment of the National Institutes of Health (NIH) Office of Research Innovation, Validation, and Application (ORIVA) and its critical mission to prioritize human-relevant research and testing. Its development represents a vital opportunity to make measurable progress in modernizing science and the practical application of such methodologies. The creation of this office provides a necessary platform to better coordinate efforts across NIH and other federal agencies, ensuring that the development of new approach methodologies (NAMs) is not siloed but integrated into an agency-wide strategy.

It is critical that this office be established promptly to achieve the objectives outlined in agency strategy reports and roadmaps, which have consistently emphasized the need to advance non-animal methods (e.g., *Toxicity Testing in the 21st Century: A Vision and a Strategy* [2007],[i] *A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States* [2018],[ii] *Catalyzing the Development and Use of Novel Alternative Methods* [2023],[iii] *Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies* [2024],[iv] and the *Roadmap to Reducing Animal Testing in Preclinical Safety Studies* [2025][v]). Its prompt establishment is also necessary if the U.S. is to maintain a leadership role in the global scientific community, as other countries and regions are setting forth their own detailed plans for transitioning to predictive non-animal research and testing.

ORIVA's establishment aligns with the recently released *Make Our Children Healthy Again Strategy Report*[vi] and *Make Our Children Healthy Again Assessment*,[vii] which emphasize the need to invest in "[NAMs], such as organ-on-a-chip, microphysiological systems, and computational biology" that are more human-relevant and provide the opportunity for "more predictive insights into chronic disease mechanisms," compared to the "animal studies that often fail to replicate complex human conditions."

ORIVA should focus exclusively on reliable and relevant non-animal methods to ensure that biomedical research and toxicology testing keep pace with 21st-century technological acceleration. Given the longstanding prioritization of animal testing over the past century, it is appropriate to pursue a strategic shift toward offices such as ORIVA, which harness advances in science and technology. As our understanding of human biological processes improves and new technology emerges, scientists are increasingly taking up modern, non-animal methods that reflect key aspects of human biology, metabolism, and physiology, and have shown greater reproducibility.

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Furthermore, non-animal methods provide the opportunity for personalized treatment plans. Adverse outcomes and disease states in humans can depend on genetic background, physiology, pre-existing disease status, lifestyle, life-stage, and co-exposure. *In vitro* test methods can use a variety of human cells from diverse donors, representing human population diversity and variability. For example, *in vitro* studies can directly compare healthy and diseased human tissues or can incorporate precision medicine techniques that provide personalized data. They can also be high-throughput, which enables faster and broader coverage of the biological space. Additionally, computer modeling can be used in combination with *in vitro* tests, exposure monitoring data, and well-constructed epidemiological studies to better understand effects on susceptible populations. By leveraging these human-derived technologies, ORIVA can ensure that NIH research effectively addresses public health.

ORIVA can help NIH accomplish its April 2025 goals to "expand funding and training in non-animal approaches and awareness of their value in translational success," expand "[i]nfrastructure for non-animal approaches" to "make these methods more accessible to researchers," develop training for grant reviewers to "address any possible bias towards animal studies and integrate experts on alternative methods into study sections," update grant evaluation criteria, and "publicly report on research spending annually to measure progress toward reduction of funding for animal studies and an increase in funding for human-based approaches."[viii] ORIVA is the only office in NIH history that has been charged with this mission, one that the research community and public have been eager to see meaningfully implemented.

We also commend the proposed establishment of the Office of Research Economics, Planning, and Analysis (OREPA). To allocate limited federal resources efficiently, OREPA should employ the use of systematic reviews to guide changes to the agency's research portfolio. Systematic reviews are a critical component of guiding valuable research and reducing waste in research funding. They can incorporate "evaluation criteria that assess methods based on their suitability for the research question, context of use, translatability, and human relevance."[ix] As such, they can inform NIH on which models should be refused further funding and which models warrant greater agency support. OREPA should conduct or commission (from unbiased, balanced parties) systematic reviews that can assist the office in calculating the return on investment received by the public from the results of previously funded animal experiments and should use this data to guide necessary improvements to NIH's research portfolio and priorities.

Thank you for the opportunity to comment on these important measures.

Sincerely,

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[i] National Research Council. *Toxicity Testing in the 21st Century: A Vision and a Strategy*. National Academies of Sciences, Engineering, and Medicine; 2007. Accessed January 26, 2026. https://doi.org/10.17226/11970

[ii] Interagency Coordinating Committee on the Validation of Alternative Methods. *A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States*. National Toxicology Program; 2018. Accessed January 26, 2026. https://dx.doi.org/10.22427/NTP-ICCVAM-ROADMAP2018

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[vii] Make America Healthy Again Commission. *The MAHA Report*. The White House; 2025. Accessed January 20, 2026. https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf

[viii] National Institutes of Health. NIH to Prioritize Human-based Research Technologies. nih.gov. April 29, 2025. Accessed January 23, 2026. https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies

[ix] *Ibid*