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National Institutes of Health
Division of Program Coordination,
Planning, and Strategic Initiatives
(DPCPSI)
5601 Fishers Lane,
Rockville, MD 20852

Submitted via: DPCPSIreorgcomments@nih.gov

Re: Proposed Reorganization: Establish ORIVA and OREPA within DPCPSI (Office of the Director, NIH)

To Whom It May Concern,

Americans for Medical Progress (AMP) appreciates the opportunity to comment on the National Institutes of Health's (NIH) proposed reorganization to establish the Office of Research Innovation, Validation, and Application (ORIVA) and the Office of Research Economics, Planning, and Analysis (OREPA) within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). As a national nonprofit advocating for biomedical research, AMP supports a balanced, evidence-based research ecosystem that fosters innovation and new technologies while recognizing the vital importance of animal studies where scientifically necessary.

AMP appreciates NIH's intent for ORIVA to strengthen interagency coordination on innovation, New Approach Methodologies (NAMs), scientific reproducibility, and regulatory translation. To strengthen its long-term effectiveness and ensure NIH's strategy remains grounded in scientific reality and public health needs, AMP offers the following recommendations, elaborated further below.

Key Recommendations

1. Adopt a standardized definition of "New Approach Methodologies (NAMs)" grounded in the full 3Rs (Replace, Reduce, Refine), not replacement alone.
2. Establish a third ORIVA division (or formal office function) dedicated to scientific integration, ensuring NAMs are developed collaboratively with appropriate animal models in support of translational validity.
3. Ensure ORIVA leadership, staffing, and advisory mechanisms reflect the full translational research ecosystem, including scientific, veterinary, animal care, and regulatory expertise relevant to NAMs development, qualification, validation, standardization, and integration with animal studies.
4. Provide clear, consistent, and transparent communication and engagement opportunities for stakeholders. This includes providing regular public comment opportunities and setting realistic expectations about where animal models remain essential and where NAMs are ready to scale.

Recommendation 1: Adopt a standardized definition of NAMs grounded in the full 3Rs
AMP urges NIH to adopt and consistently apply a standard definition of NAMs, as the current ambiguity about what constitutes NAMs has hindered implementation, affected stakeholder trust, and complicated policy development.

Importantly, AMP urges NIH to ensure the definition reflects the full 3Rs framework, not replacement alone. While replacement is a goal where scientifically appropriate, a replacement-only framework does not reflect the current translational ecosystem and may unintentionally stifle innovation and the development of important medical therapies. Many meaningful biomedical research advances will continue to involve reduction and refinement, as well as complementary approaches with animals that strengthen study design, reproducibility, and predictive value.

A clear, federally harmonized NAMs definition will improve cross-agency consistency in program execution and communication, clarity for grant applicants and reviewers, and most importantly, public understanding of what NAMs are and are not.

Recommendation 2: Establish a third ORIVA division dedicated to scientific integration.
Although the proposed ORIVA structure includes two suboffices—Division for Accelerating Innovation in Biomedical Research and Division of the National Interagency Center for the Evaluation of Alternative Test Methods—the current framework does not clearly identify an organizational home for a central scientific and policy challenge: integration.

Translational biomedical research must not operate as a choice between approaches; it requires sustaining essential animal models while responsibly advancing and integrating New Approach Methodologies (NAMs). Allowing integration to become an afterthought risks undermining NIH's broader goal of accelerating biomedical research. It should instead be recognized as a central scientific governance challenge requiring intentional planning, dedicated federal resources, and appropriate expertise.

To address this, AMP recommends NIH establish a third division or formal office function within ORIVA, such as "Division of Integrated Translational Models and Research Validity." Its function should include explicit responsibility for:

- Integration strategy across animal models and NAMs;
- Fit-for-purpose and context-of-use standards and evidence expectations;
- Translational validity guidance, including clarity on limitations and uncertainty;
- Ecosystem continuity (workforce, infrastructure, capacity) to avoid attrition of research capabilities that remain essential to biomedical research and medical therapies; and
- Cross-agency coordination to prevent inconsistent expectations or fragmented roll-out.

AMP views this as an additive, stabilizing structure that strengthens ORIVA's mission rather than expanding the scope beyond NIH's intent.

Recommendation 3: Ensure ORIVA staff includes the full range of scientific and veterinary expertise needed for implementation.
To be successful, ORIVA must be designed not only as an innovation hub but also as an implementation and coordination body capable of managing responsible research translation. AMP strongly recommends NIH ensure ORIVA leadership, staffing, and advisory mechanisms reflect the full spectrum of expertise relevant to this mission, including:

- Translational and comparative biology;
- Animal model development and evaluation;
- Laboratory animal medicine and veterinary oversight;
- Animal welfare science and refinement techniques;
- NAMs development; and

- NAMs validation, qualification, reproducibility, and standardization;

Comprehensive expertise is necessary to ensure ORIVA is positioned to advance NAMs without destabilizing the broader biomedical research field or introducing scientific and regulatory risk.

Recommendation 4: Strengthen stakeholder communication while setting realistic expectations.
AMP urges NIH to pair ORIVA implementation with clear, consistent communication that clearly conveys what NAMs can and cannot yet achieve and affirms the continued necessity of animal studies. This is vital for ensuring ORIVA is implemented in a manner that supports long-term scientific credibility and public trust. Specifically, we encourage NIH:

- Clearly explain why animal models are still crucial in many fields of research, and why;
- Distinguish aspirational goals from current scientific readiness; and
- Avoid messaging that implies NAMs can entirely replace animal research.

Furthermore, AMP recommends NIH provide regular opportunities for stakeholder participation, such as public listening sessions and workshops, implementation updates and milestone reporting, and comment opportunities to solicit feedback from researchers, institutions, veterinarians, animal welfare and oversight professionals, and patient stakeholders. Comment opportunities should allow sufficient time (e.g., 60 days) for meaningful stakeholder engagement.

Conclusion
AMP appreciates NIH's efforts to strengthen innovation, reproducibility, and responsible non-animal approaches, while supporting regulatory translation and public health. AMP believes ORIVA can be a meaningful and constructive mechanism to support these goals if NIH ensures definitional clarity, builds an explicit integration and research assurance function, reflects the full translational ecosystem in its staffing and advisory structures, and commits to transparency and ongoing stakeholder engagement.

Thank you for the opportunity to comment on this proposal and for NIH's continued leadership in advancing life-saving biomedical research.

Sincerely,

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