PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027-2031 (NOT-OD-26-047)

Submitted via form.

Please include any comments on NIH's Goals across the three Priorities articulated in the Strategic Plan Framework, including potential benefits, drawbacks or challenges, and other areas of focus for consideration.

Priority 1: Research Areas

On behalf of People for the Ethical Treatment of Animals—PETA entities have more than 10.4 million members and supporters globally, and PETA U.S. is the largest animal rights organization in the world—we submit the following recommendations for strengthening the NIH-Wide Strategic Plan for Fiscal Years 2027- 2031 so that it better supports research that improves human health.

A substantial body of scientific literature shows that experiments on animals are flawed and divert financial and intellectual resources away from more reliable, human-relevant technologies. Inherent biological differences between species are the primary reason findings in animals fail to translate to humans, even when studies are well designed. As a result, animal experimentation hinders the generation of meaningful knowledge about human disease, delays progress in disease prevention, and impedes the development of safe and effective treatments. Consider:

- 95% of new drugs fail in human clinical trials (https://ncats.nih.gov/research/research-activities/ntu), despite having passed preclinical safety and efficacy testing in animals.
- Nearly 90% of basic research—much of it conducted in animals—does not lead to routine clinical use within 20 years (https://doi.org/10.1016/s0002-9343(03)00013-5).
- Up to 89% of preclinical studies, representing an estimated $28 billion annually, cannot be reproduced (https://doi.org/10.1371/journal.pbio.1002165).
- Animal tests fail to identify potential human adverse drug effects in approximately 81% of cases (https://doi.org/10.1016/j.yrtph.2012.09.002).

Entities
- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Netherlands
- PETA Foundation (U.K.)

These findings underscore the need for NIH to critically evaluate the scientific value of the models it funds. First, the NIH-wide strategic plan should include a clear commitment to end the use of animals in research areas where there is substantial evidence that the data do not reliably translate to humans and where scientifically valid human-relevant methods exist. Although NIH-funded institutions must comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (https://grants.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf), currently, it only requires that researchers and Institutional Animal Care and Use Committees consider non-animal methods. Because non-animal methods are not required, animal use continues even when more predictive human-based approaches are available.

Second, once the Office of Research Economics, Planning, and Analysis (OREPA) is established (https://dpcpsi.nih.gov/proposed-reorg-establish-oriva-orepa), systematic reviews should be performed to evaluate NIH's research portfolio and guide funding decisions. Please see more about this topic in our response to Priority 3.

Third, in cases involving companion animal clinical trials, or where the work directly benefits the individual animals involved, protections comparable to those used in human subject research should apply (https://doi.org/10.1017/S0963180119000732). These protections should include independent ethical review, transparent harm-benefit analysis, and clear demonstration that no scientifically valid, species-relevant alternative can address the research question.

By adopting these measures, NIH can support the development of innovative human-based technologies that improve healthcare outcomes and deliver life-changing treatments for patients.

Priority 2: Research Capacity

To develop an interdisciplinary research workforce and improve current research infrastructure, the NIH-wide strategic plan should commit to ending funding for animal-based infrastructure and expanding investment in non-animal research infrastructure, including intramural programs. Redirecting resources toward human-based research tools will accelerate biomedical innovation, create new scientific career opportunities, and improve research efficiency while advancing human health.

We commend NIH for its $150 million investment in human-based research (https://www.nih.gov/news-events/news-releases/nih-invests-150-million-human-based-research-reduce-use-animal-models) and for launching the Standardized Organoid Modeling (SOM) Center (https://www.nih.gov/som). However, these investments remain small relative to NIH's support for animal experimentation (https://www.gao.gov/products/gao-25-107140). Many federally funded researchers also continue to receive training primarily in animal-based methods and have limited exposure to advanced human-relevant technologies. Transitioning to these approaches often requires retraining, new laboratory equipment, and access to interdisciplinary expertise.

For these reasons, non-animal methods require substantially greater support to reach their full potential. We recommend that NIH:

- Dedicate funds to establishing additional SOM-style Centers (or expanding the SOM Center itself) to standardize and validate organ-chips, human tissues slices, and reconstructed human tissue models—in addition to organoids.
- Expand the National Center for Advancing Translational Sciences Tissue Chip for Drug Screening program to support broader use of tissue chips in basic research and disease modeling.
- Create funding mechanisms to help laboratories transition from animal use to animal-free technologies.
- Develop training grants and fellowships focused on animal-free methodologies.
- Partner with research institutions to create accessible training programs in non-animal methods that can be recognized in NIH grant applications.

NIH should also address continued investment in ineffective and outdated animal-based infrastructure. Decades of public funding for National Primate Research Centers (NPRCs) have not produced proportional improvements in human health, while monkeys in these facilities continue to suffer, exhibiting physiological and psychological signs of extreme distress. NPRCs have been repeatedly cited for animal welfare violations and pose a threat to public health due to zoonotic disease outbreaks associated with monkey importation and the risk of animal escapes, incidents of which have been documented. We urge NIH to include a pathway to transition these centers into hubs for non-animal research, with support for placing remaining animals into sanctuaries or temporarily retiring them in place, as is being explored with the Oregon NPRC.

Additionally, NIH must stop funding animal experiments conducted at foreign institutions, where oversight cannot be assured. Between 2011 and 2021, foreign facilities received $2.2 billion in NIH funding for animal experiments, despite the agency having zero oversight on how these funds are used. NIH does not inspect these laboratories or arrange for independent inspections to ensure compliance with even the minimal U.S. animal welfare standards. Federally funded research is intended to serve the interests of the American public. However, the core issue is not merely oversight. Public funds should not support experiments on animals—whether conducted domestically or abroad—when human-relevant, animal-free research methods are available and necessary to advance biomedical progress. Directing these funds toward animal-free approaches is essential to ensure translatable outcomes that can lead to effective treatments and cures.

Priority 3: Research Operations

A core objective within the NIH-Wide Strategic Plan is promoting public accountability and social responsibility. To meet this objective, the Plan should include a clear commitment to quantitatively track and publicly report both 1) the number of animals used in NIH-supported research and the purposes for which they are used, and 2) how NIH funding is allocated between animal-based and human-based research approaches.

The Government Accountability Office's 2019 report on animal use in research

(https://www.gao.gov/products/gao-19-629) recommended that agencies propose metrics to help them better monitor progress in reducing animal use and to report their progress to the public. Implementing such metrics at NIH would provide an empirical foundation for evaluating the impact of new method adoption; guide grant allocation toward methods that improve reproducibility and cost effectiveness; align with reducing and replacing the use of animals; and strengthen the agency's ability to prioritize activities. At a minimum, reporting the number of animals used in NIH-supported research and the endpoint/purpose is a practicable step, as demonstrated by reporting systems in the European Union and the United Kingdom.

Transparency in outcomes must be matched by transparency in spending. In its April 2025 announcement (https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies), NIH stated that it would "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." While this commitment was a promising first step, no mechanisms or data have been described or publicly released. Without systematic tracking and public reporting of funding allocations, the agency cannot determine whether it is meaningfully advancing its stated goals for research modernization and transparency. Incorporating both animal-use metrics and funding allocation reporting into the NIH-Wide Strategic Plan would meaningfully advance the agency's commitments to transparency, evidence-informed decision-making, and public accountability.

As mentioned in our response to Priority 1, once OREPA is established, systematic reviews should be performed to evaluate NIH's research portfolio and guide funding decisions. These reviews can assess whether proposed methods are scientifically valid, translatable, and relevant to human biology (https://brill.com/edcollbook-oa/title/35072; https://ntp.niehs.nih.gov/sites/default/files/2024-03/VWG_Report_27Feb2024_FD_508.pdf; https://doi.org/10.1177/01410768221093551). For research areas where uncertainty remains about whether animal use is beneficial, OREPA should conduct systematic reviews to determine whether the animal experiments in question have contributed meaningful clinical benefit. Additionally, while experiments on animals continue, a system of analysis for a "risk threshold" or "upper limit" for harm, similar to that employed in research on humans, should be implemented. Harm-benefit analyses can be performed that include an ethical perspective and consideration of lifelong harm inflicted on animals, as well as a consideration of benefits that includes past failures of similar models. The findings from systematic reviews and harm-benefit analyses should inform future funding priorities. Considering the heightened ethical concerns around animal use, it is reasonable to require clear, prospective evidence of human relevance and realistic anticipated clinical benefit as a condition for NIH funding.