National Institutes of Health Request for Information on Enhancing Rigor, Transparency, and Translatability to Improve Biomedical Research Involving Animal Models

Response from People for the Ethical Treatment of Animals (PETA)

As NIH has acknowledged in this Request for Information, the use of animals in biomedical research continues to face grave challenges in ensuring scientific rigor. Animals are being used in invasive and deadly experiments even when they poorly represent the human disease they are intended to model. Numerous scientific studies and reviews reveal that experiments on animals fail to lead to effective treatments and cures for human diseases, including the top killers in the U.S. The NIH's own National Center for Advancing Translational Sciences reports that new drugs (which are tested for safety and efficacy in other animals) fail in about 95% of human studies.¹ Reliance on animal models is diverting funds from more promising areas of research and delaying the development of effective drugs and treatments.

Though much could be done to address the poor quality of animal research, including the pervasive lack of research reproducibility, the confounding factors inherent in keeping animals in unnatural laboratory environments, and poorly-planned studies, no amount of improvement in these areas can address the *fundamental* inability of other species—even other primates—to serve as analogs for understanding human health and human biology. Poor rigor in animal experiments cannot be overcome by simply improving study design. This is because external validity, or the "extent to which research findings derived in one setting, population or species can be reliably applied to other settings, populations and species,"² can never be achieved. Intrinsic biological and genetic differences among species contribute significantly to inescapable problems in extrapolating results from nonhuman animals to humans, even in the best-controlled, best-executed study designs.

NIH must focus its efforts on redirecting funding from experiments on animals and instead towards providing greater support for non-animal, human-relevant research methods. To accomplish this goal, scientists with People for the Ethical Treatment of Animals have developed a robust blueprint titled, The Research Modernization Deal, which you can review by visiting www.peta.org/newdeal.

A paradigm shift in the current research culture is critical for this change. Several major problems exist, including the perverse incentive structure to publish above all else, the pressure on students and young investigators to engage in the antiquated animal-based research methods of their predecessors, and the lack of a diversity of expertise in the committees that review research proposals for funding consideration.

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Unfortunately, success within the biomedical research community is often measured in terms of publication metrics. Publishing a greater number of papers in what are considered high-impact journals³ improves a scientist's odds of receiving federal funding for research, which in turn generates more papers, which begets more funding, and so on, in an effort to advance a researcher's career-hence the common phrase in academia to "publish or perish." This emphasis on publishing leads to sloppy research practices, as scientists often rush to push out results at any cost, instead of being allowed the time and funding to learn superior human-relevant and animal-free techniques, invest in appropriate equipment, and ensure their methods are sound.⁴

Presently, and for much of human history, the biomedical research community has placed a bewildering amount of time, money, and effort manipulating the anatomies, physiologies, and genomes of other species. Older scientists who have been using the same archaic animal-based techniques that their own mentors used, and who have neither been pushed nor felt they had the time to learn more advanced non-animal methods, are the ones training younger scientists. Graduate students being trained in laboratories using animal-based techniques are rar elyexposed to the breadth of human-relevant research methods that exist and are pressured to design and perform experiments on animals in order to quickly publish papers.⁵ To break this cycle, it is imperative that NIH robustly support, coordinate, and fund the training of young scientists in animal-free, human-relevant research methods.

In addition, NIH Center for Scientific Review must ensure a diversity of expertise within its Study Sections. Presently, Study Sections appear to be dominated by individuals with expertise only in animalbased methods, and who may have a vested interest in seeing animal experimentation persist as a dominant research paradigm. Or they may favor these proposals simply because this is the area with which they are most familiar. This means that scientists who submit proposals to address human health issues and answer important research questions using animal-free methods are likely being denied adequate consideration, as there are few reviewers who understand or support their strategies. NIH must ensure that the at least half of the membership of each Study Section is made up of scientists whose primary expertise is in safe and effective human-based practices.

To enhance rigor, reproducibility, and translation of research findings, NIH must now take the necessary steps to end the funding of experiments on animals that have repeatedly and overwhelmingly failed to provide effective treatments and cures for human conditions. With greater investment in exciting and innovative non-animal methods and bold policy initiatives, researchers can safely develop far more promising therapies for humans and also alleviate the immense suffering of tens of millions of animals who are currently used in experiments each year.

References

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