Request for Information (RFI): Request for Information (RFI) on the FY 2021-2025 National Institutes of Health (NIH) - Wide Strategic Plan Framework

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03/23/2020 at 05:44:35:832 PM

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Type of Organization

Advocacy Group

Role in Organization

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Please select yes/no if you are responding on behalf of your organization

Yes

Please include any comments on the following:

Cross-Cutting Themes articulated in the framework, and/or additional cross-cutting themes that may be considered.

There are opportunities within the following cross-cutting themes to reduce the use of animals and modernize biomedical research. •Optimizing Data Science and the Development of Technologies and Tools: NIH must increase funding in these areas only where the data, technologies, and tools are based in human biology, without the use of animals. •Promoting Collaborative Science: Where investigators lack the capabilities to conduct human-based research, NIH must help pair these individuals with others who have expertise to assist them in a transition away from experiments on animals. •Addressing Public Health Challenges Across the Lifespan: Diseases primarily affecting individuals in early and late life are often studied using crude experiments on animals, despite an abundance of evidence that these methods are failing. NIH must prioritize non-animal research for these conditions. An additional cross-cutting theme should be added: Eliminate Reliance on Non-Human Animals. NIH reports that novel drugs fail in 95 percent of human studies, even though they appeared safe and effective in preclinical experiments using animals (1). A 2014 analysis published in The BMJ found that—contrary to public perception—studies using animals largely have not furthered knowledge in the field of human health or led to the development of treatments for conditions

affecting humans (2). Experiments on animals lack both internal and external validity, meaning they are usually poorly executed, but even if the experimental methods were improved, the results would not translate to humans. The difficulties in applying data derived from animals to human patients are compounded by confinement and unnatural conditions of laboratory life, which thwart animals' ability to engage in natural behaviors. This deprivation contributes to their stress and alters their physiology and neurobiology, causing them to exhibit various psychopathologies. Importantly, the fact that animals in laboratories have altered physiology and neurobiology means that they will never be good "models," even for members of their own species who are free-roaming. Along with mounting evidence that experiments on animals do not reliably translate to humans and the increasing development and implementation of technologies that can supplant animal use in laboratories, our society has witnessed growing moral concern regarding animal experimentation. An August 2018 poll conducted by the Pew Research Center found that a majority of U.S. adults, the taxpayers who fund the NIH, oppose the use of animals in scientific research (3). If the public were fully aware of the mountain of evidence that studies on animals may very well be hampering the development of effective treatments, opposition would likely grow substantially. If our finite public funds are to be used responsibly, they must fund research, whether basic or applied, that leads to effective treatments for humans. The evidence that basic and applied research involving animals is impeding the development of treatment and cures for human ailments has not heretofore prompted NIH to rethink research and funding priorities sufficiently. However, such a paradigm shift is crucial. 1. https://ncats.nih.gov/files/NCATS-factsheet.pdf 2. https://doi.org/10.1136/bmj.g3387 3. https://www.pewresearch.org/fact-tank/2018/08/16/americans-are-divided-over-the-use-of-animals-in-scientific-research/

NIH's priorities across the three Objectives articulated in the framework, including potential benefits, drawbacks or challenges, and other priority areas for consideration.

Objective 1 can only be achieved by prioritizing human-based research and eliminating the use of animals. One of the efforts that NIH must take to fulfill this objective is to ensure that study sections are comprised of individuals with ample expertise in non-animal research and not dominated by those vested in the use of animals. Objective 2 can be achieved, in part, by providing additional financial assistance to investigators who wish to switch from animal-based to human-based methods; and by ceasing funding to train young investigators in animal methods. Regarding Objective 3, animal experiments lack internal and external validity and are in direct conflict with Scientific Integrity, Social Responsibility, and Good Scientific Stewardship. An additional objective should be added: Using Evidence-Based Methods to Improve Human Health Research. We propose a step-wise approach. 1. Immediately Eliminate Animal Use in Areas in Which Animals Have Been Shown to be Ineffective "Models" for Humans and Their Use has Impeded Progress: Multiple reviews have documented the failure of animal use to benefit human health in specific disease areas. Animal experiments in these areas should be ended as soon as possible and replaced with more effective and efficient non-animal research methods. 2. Increase Funds for Non-Animal Studies and Decrease Funds for Animal Studies: As long as part of the NIH budget goes to experiments on animals, the U.S. will be stalled in developing effective treatments for human disease. Forward-thinking scientists, some funded by NIH, are advancing and implementing methods for studying and treating diseases and testing products that do not entail the use of animals and are relevant to human health. Researchers have created human cell-derived skin models, "organs-on-chips," in silico models, and other methodologies that can replicate human physiology, diseases, and drug responses more accurately than experiments on animals do. Indeed, in its most recent five-year strategic plan, NIH announced that it would reduce and replace animal experiments. NIH must now take the next step and end the funding of experiments that have failed to provide effective treatments and cures. With greater investment in exciting and innovative non-animal methods and bold policy initiatives, far more promising cures and treatments for humans can be developed. 3. Conduct Critical Scientific Reviews of Previous Animal Studies to Identify the Areas in Which the Use of Animals Can Be Immediately Ended: For those areas of investigation where there is still some question as to whether the use of animals is beneficial, a thorough systematic review should be conducted to determine the efficacy of using animals. The National Academy of Medicine, formerly the Institute of Medicine, completed an examination of the scientific necessity of using chimpanzees in behavioral and biomedical research. That effort revealed that harmful studies had been approved, funded, and conducted for years, even though there were alternative methods in virtually every area in which chimpanzees were being used. Institutional oversight bodies and funding agencies had given their stamp of approval to these protocols. However, as we now know, the review processes in place were simply inadequate.

Future opportunities or emerging trans-NIH needs.

In addition to an overall paradigm change in NIH's reliance on the use of non-human animals, there are a number of areas of NIH intramural and extramural research which should be ended immediately. NIMH must end its support and conduct of psychological and other poorly-designed studies. Elisabeth Murray, an investigator at NIMH, carves out a section of a monkey's skull, injects toxins into the brain, suctions out portions of it or burns them, causing permanent and traumatic damage. She then repeatedly terrifies the monkeys with realistic-looking, animated artificial snakes and spiders. When Murray has finished with them, they may be killed or recycled into other experiments, to be further tormented. NIH has thrown $36 million to Murray's laboratory in the past 13 years, but not one treatment or cure for humans has come out of it in 30 years. NIMH Director Joshua Gordon has voiced his support for cruel experiments on animals that are notoriously poor models for studying human disease. Gordon has indicated he intends for the Institute to continue to fund the forced swim test, tail suspension test, foot shock, and social defeat experiments, where small animals are made to swim to keep from drowning, taped up by their sensitive tails, subjected to electric shock, and where experimenters incite some animals to attack and intimidate others, respectively. Nothing about these tests "models" complex human neuropsychiatric disorders and reliance on them is consistently cited as a leading

reason why so many neurobehavioral drugs fail in human trials. Another area of NIH funding that must end immediately is support for the use of non-human animals in sepsis experiments. Numerous peer-reviewed publications have described the inability of mice and other non-human animals to function as appropriate experimental models of human sepsis due to inherent genetic and physiological species differences, the disconnect between methods of experimental sepsis induction in non-human animals and the way that sepsis manifests in humans, and significant animal-welfare concerns that further confound study results. More than 60 clinical trials have been undertaken to test novel treatments for sepsis. However, all have failed to yield any benefit for humans. Clinicians cite unconstructive tests on animals as a primary reason for these failures and call for human-relevant methods to be adopted. For NIH to continue to spend taxpayers' dollars on experiments it has long known to lack translatability to sepsis in humans baselessly disregards the statutory and regulatory criteria that govern NIH's funding authority. Additionally, NIH must reverse its plans to support centralized infrastructure for experiments on marmosets, which have less to do with good science and everything to do with convenience. Marmosets are complex, unique, social individuals with the capacity to experience a wide range of emotions. In captivity, they are susceptible to many infectious pathogens—and they can also succumb to painful and potentially deadly marmoset wasting disease. Thus, the experimental use of marmosets introduces additional ethical concerns. By ramping up funding to increase the supply of marmosets for laboratories, NIH is doubling down on a failed enterprise.