



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 115,000 Researchers

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May 3, 2022

The Honorable Rosa DeLauro
Chairwoman
U.S. House Appropriations Committee
Subcommittee on Labor, Health and Human
Services, Education, and Related Agencies
Washington, D.C., 20515

The Honorable Tom Cole
Ranking Member
U.S. House Appropriations Committee
Subcommittee on Labor, Health and Human
Services, Education, and Related Agencies
Washington, D.C., 20515

Dear Chairwoman DeLauro and Ranking Member Cole,

As the largest coalition of biomedical researchers in the United States, representing 28 member societies and 115,000 individual scientists, the Federation of American Societies for Experimental Biology (FASEB) appreciates President Biden's continued commitment to science, biomedical innovation, and pandemic preparedness as outlined in the Fiscal Year (FY) 2023 budget request. To achieve revolutionary change in these areas and strengthen the nation's competitive edge on the global stage, robust investments in animal research and scientific infrastructure remain essential.

Large Animal Translational Research

FASEB urges the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (LHHS) to include language in the FY23 appropriations bill and report that supports and expands large animal translational research conducted at the National Institutes of Health (NIH). Strengthening the global health landscape to combat future pandemics, as outlined in the President's budget request, is a laudable goal that will require strategic support for the resources scientists rely on, including large animals. Although most research proposals (e.g., more than 95 percent) involve small animals such as rodents, studies with larger, long-lived species such as canines, felines, and nonhuman primates can more effectively answer complex research questions given their biological similarities to humans. For example, canines serve as powerful models for understanding the genetic and environmental factors influencing diseases such as cancers, heart disease, and neurological disorders because they naturally develop—and similarly present—the same diseases and conditions. Other non-rodent species such as hamsters, pigs, llamas, guinea pigs, and ferrets are essential models for studying diseases such as cardiovascular disease and viral infections given their similar anatomy and immune responses to humans. In comparative medicine, these similarities strengthen research rigor, reproducibility, and translatability and enables accelerated advancement of potential drugs and therapies compared to models with lower predictability. Therefore, sustained federal support for large animal translational research will ensure that scientists have the resources and expertise necessary to maintain ongoing studies, explore emerging research areas, and prepare for future global health threats.

Full members: The American Physiological Society • American Society for Biochemistry and Molecular Biology • American Society for Pharmacology and Experimental Therapeutics • American Society for Investigative Pathology • American Society for Nutrition • The American Association of Immunologists • American Association for Anatomy • Society for Developmental Biology • Association of Biomolecular Resource Facilities • The American Society for Bone and Mineral Research • American Society for Clinical Investigation • Society for the Study of Reproduction • The Endocrine Society • American College of Sports Medicine • Genetics Society of America • The Histochemical Society • Society for Glycobiology • Association for Molecular Pathology • Society for Redox Biology and Medicine • Society For Experimental Biology and Medicine • American Aging Association • Society of Toxicology • Society for Leukocyte Biology • American Federation for Medical Research • Environmental Mutagenesis and Genomics Society • Shock Society • **Associate members:** The American Society of Human Genetics • The Society for Birth Defects Research & Prevention

FASEB recognizes the concerns the Appropriations Committees have outlined in previous funding bills related to the use of animals in research and acknowledges the emerging field of research with non-animal models such as organs on chips, cell culture, and computer simulations. These models play a vital role in supplementing research with animals, often by providing preliminary information for scientists to differentiate particular drug targets or biological pathways. However, such techniques cannot be used alone to replace animal studies because they do not provide comprehensive insight into mechanisms affecting the whole body, including complex diseases and disorders. Additionally, nonanimal models must be validated in animals to ensure safety and efficacy, further underscoring the essential need and value of continued support for animal studies.

Scientists remain dedicated to the established ethical, legal, and scientific standards that strictly regulate animal research, as cited in the United State Department of Agriculture Animal and Plant Health Inspection Service [2021 Annual Impact Report](#) which found 96 percent of licensees and registrants in substantial compliance with the Animal Welfare Act. Beyond the regulatory requirements, scientists, veterinarians, and animal care staff extend compassionate, round-the-clock care for research animals because they recognize that high-quality oversight ensures excellent science and, more importantly, that humane care for animals is our societal responsibility. Finally, scientists are committed to the 3R's—reducing animals to the most appropriate numbers, refining research practices, and replacing animals with nonanimal options where possible—when designing, reviewing, and conducting research studies. However, to fully implement the 3Rs, a significant number of comparative and validation studies with animals are needed. Therefore, FASEB recommends that the House LHHS Appropriations Subcommittee include language in the FY23 appropriations bill and report that specifically funds validation studies for NIH researchers.

Availability & Transportation of Nonhuman Primates

The COVID-19 pandemic presented numerous scientific and infrastructural challenges that can inform future appropriations strategies. Chief among these challenges was the lack of availability of nonhuman primates, animals that remain indispensable for vaccine research and development. The National Primate Research Centers (NPRCs)—a network of seven medical research centers across the U.S.—remain a steadfast pillar in advancing human health by breeding and caring for nonhuman primates, as seen in the development and distribution of the COVID-19 vaccines. However, their work is currently limited due to global and national constraints. During the pandemic, researchers [struggled to acquire nonhuman primates](#) to meet the rising demand for studies on SARS-CoV-2. This was further exacerbated when China banned exports at the beginning of the pandemic. The unexpected pivot to COVID-19 research and enduring lack of nonhuman primates forced numerous investigators to halt ongoing studies into other diseases that rely on these animals, including tuberculosis and HIV/AIDS. To achieve realistic pandemic preparedness, research centers specializing in disease research such as the NPRCs must have the resources, staff, and infrastructure to swiftly respond. For instance, as novel SARS-CoV-2 variants continue to emerge, NPRCs will need adequate support to continue research and development of a potential universal coronavirus vaccine. FASEB urges the House LHHS Appropriations Subcommittee to acknowledge the critical need for nonhuman primate research and allocate additional funding for the NPRCs.

In addition to support for the NPRCs, FASEB urges the House LHHS Appropriations Subcommittee to address the ongoing refusal of numerous airlines to transport animals for research purposes. This issue has compounded the current shortage of nonhuman primates as noted above and jeopardizes biomedical research in the U.S. more broadly by inhibiting researchers' access to the appropriate animals essential for addressing pressing public health questions. As competing nations accelerate investments in research and development, we are concerned that leaving this issue unresolved will unnecessarily delay U.S. research productivity, weaken our ability to respond to future public health crises, and compel investigators (both academic and biopharma) to pursue opportunities elsewhere. China, for example, is [heavily investing](#) in nonhuman primate research and infrastructure and is on track to surpass the U.S. in nonhuman primate research capacity and expertise. In an ever-changing 21st century economy, retaining domestic talent and safeguarding U.S. scientific resources—including the supply and transport of nonhuman primates—is critical for achieving national and economic security. Thus, FASEB encourages the House LHHS Appropriations Subcommittee to include language that directs NIH to collaborate with the Centers for Disease Control and Prevention and the Food and Drug Administration to develop a federal plan that ensures the long-term support, breeding locations, veterinary oversight, and enrichment and social needs of nonhuman primates in the U.S. to bolster availability of animals to researchers, similar to language included in the Senate LHHS FY22 Appropriations [explanatory statement](#) (see pg. 161, “*Research with Nonhuman Primates*”). To facilitate this strategy and develop a coordinated federal response, FASEB recommends collaborating with the House Appropriations Subcommittee on Transportation, Housing and Urban Development, and Related Agencies.

Scientific Infrastructure

Research facilities, many of which centrally house and care for research animals, provide essential tools and expertise investigators need to conduct research experiments in a timely and rigorous manner. Studies with large animals in particular require significantly more professional oversight, time, care, and space. In keeping with President Biden's efforts to advance infrastructure development, FASEB recommends specific investments in scientific infrastructure to ensure research facilities keep pace with scientific needs. This includes but is not limited to: facility building and renovation, acquisition and maintenance of cutting-edge instrumentation, and professionally trained staff that provide essential animal care and technology training. By investing in scientific infrastructure and staff talent, investigators will have the resources to drive biomedical research forward while attracting and retaining the best and brightest scientific minds, bolstering the U.S.'s competitive edge.

Reducing Administrative Burden

A central tenet of the 21st Century Cures Act was to accelerate biomedical research to improve human health and reduce the administrative burden animal researchers experience to provide more time for conducting research. As outlined in the 2018 Federal Demonstration Partnership [Faculty Workload Survey](#), investigators spend nearly half (44.3 percent) of their research time consumed by regulatory burden. This is particularly problematic for small institutions that have limited staff and resources. While FASEB appreciates the steps NIH is taking to [address](#) inconsistent and duplicative policies related to animal research, several policy concerns remain unaddressed more than five years after the law's enactment. To maximize federal investments and foster continued biomedical progress, we recommend the House LHHS Appropriations Subcommittee include language that directs NIH to provide a list of

steps the agency intends to take over the next year to reduce investigator burden, accompanied with implementation timelines and planned strategies for communicating new information with the extramural community. These details can complement existing NIH efforts—including the [2019 report](#) outlining key areas to improve and a recent [blog post](#) describing forthcoming opportunities— and help hold the agency accountable to its charge stipulated by the 21st Century Cures Act.

FASEB recognizes Congress’s concerns about the accuracy and transparency of reporting of NIH-funded research with animals, as outlined in previous House and Senate LHHS appropriations report language. However, institutions and federal agencies already have documentation protocols in place to collect information on the number and welfare of animals used in research based on individual facility needs and characteristics. Therefore, FASEB requests the Subcommittee refrain from including language pertaining to the collection and public dissemination of the total number of animals bred and used in research as this would significantly increase institutional and agency workload. Furthermore, such language is inconsistent with Congressional efforts to reduce administrative burden. While we share the Subcommittee’s commitment to enhancing animal welfare, directives to count and publicly report the total number of animals would not achieve this goal because it would consume time and resources away from formal animal care. Rather, additional resources should be allocated towards factors known to promote animal health and welfare, including environmental enrichment, expanded housing, and training for animal care staff. Ensuring institutions and federal agencies maintain flexible reporting requirements is essential towards facilitating research rigor and continuity, providing investigators and staff the bandwidth to concentrate on aspects that will generate robust scientific findings, including optimal animal health and welfare.

Continued investments in animal research and scientific infrastructure are essential for maintaining U.S. scientific leadership and forging a path forward for the next generation. FASEB urges the Senate LHHS Appropriations Subcommittee to sustain support for large animal translational research, ensure availability and transportation of nonhuman primates, and fund research facility and technology modernization. Importantly, federal support for these areas should be coupled with policies that enhance rather than hinder research productivity, as administrative burden continues to unnecessarily delay critical research studies.

Please do not hesitate to contact us should you have any questions regarding these important topics.

Sincerely,

A handwritten signature in black ink that reads "Patricia L. Morris". The signature is written in a cursive, flowing style.

Patricia L. Morris, MS, PhD
FASEB President