July 17, 2015

The Honorable Lamar Alexander, Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Patty Murray, Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The American Physiological Society (APS) appreciates the Senate HELP Committee’s bipartisan initiative to seek ways to enhance the ability of the National Institutes of Health (NIH) to contribute to the development of new treatments for disease such as drugs and medical devices. The APS is a not-for-profit professional society dedicated to advancing scientific research into how the body functions and how humans and animals can sustain themselves in the face of challenges such as disease, aging, and hostile environments. The APS was founded in 1887 and today has some 10,500 member scientists in all 50 states who work in colleges, universities, medical schools, industry, and government.

We support the letter submitted by the Ad Hoc Group for Medical Research Funding concerning the importance of sustained increases in appropriations, granting the NIH carry-over budget authority, supporting the full spectrum of research, and easing burdensome travel restrictions that hamper the ability of federal researchers to participate in scientific exchanges. We want to underscore the importance of continued support for basic research as the foundation for success in translational initiatives. Finally, we want to suggest a few ways to optimize our research investment by reducing regulatory burden.

According to a 2005 survey by the Federal Demonstration Project (FDP), regulatory compliance consumed 42% of the time that principal investigators spend on federally-funded research. A 2012 follow-up survey by the FDP found virtually the same level of effort being diverted from the direct conduct of federally-funded research to compliance activities. Both surveys also identified oversight related to studies of animals as models of human disease as one of the most time-consuming areas.
Research with animals plays an important role in medical discovery. Regulatory oversight is essential to ensure not only that research is designed and executed appropriately but also that animals are treated humanely. Nevertheless, bureaucracy and risk aversion within both federal agencies and university administration has made regulatory compliance increasingly difficult. We therefore urge the committee to consider ways to encourage NIH to find ways to simplify compliance. Two specific ideas are noted below. We would also be happy to meet with your staff to discuss this further.

**Align Full Protocol Reviews with the Length of Grants**

Every research institution that receives NIH funding must have a committee oversee research activities involving animals. This Institutional Care and Use Committee or “IACUC” ensures that all research with vertebrate animals complies with the Public Health Service Policy on the Humane Care and Use of Animals (PHS Policy). One of this committee’s responsibilities is to conduct a full review of animal procedures before the research commences. Currently NIH also requires a *de novo* review of the protocol every 3 years. However, the average length of an NIH grant is more than 4 years so many protocols have to be re-reviewed at the 3-year mark and again 1-2 years two later when the grant comes up for renewal. This creates extra work for researchers and IACUC members alike. Since NIH’s oversight policies already require researchers to seek the IACUC’s approval before making any significant changes to research procedures involving animals, NIH could reduce regulatory burden by requiring full reviews only when a grant commences or is renewed.

**Avoid Unnecessary Prescriptive Guidance**

NIH’s Office of Laboratory Animal Welfare regularly produces guidance documents intended to help institutions meet their obligations under the PHS Policy. However, risk-adverse research institutions sometimes treat these suggestions as if they were new regulations. NIH should make every effort to ensure that the regulated community can readily distinguish between suggestions and requirements.

We commend the HELP Committee for its efforts to strengthen NIH and increase its budget to expedite the development of new treatments for patients suffering from serious diseases. If you have any questions about the topics discussed above, please contact Alice Ra’anán, APS Director of Government Relations and Science Policy.

Sincerely,

Patricia E. Molina, MD, PhD
President