2016 Animal Care and Experimentation Committee Report

During 2015-2016, the Animal Care and Experimentation Committee (ACE) Committee visited Capitol Hill to advocate for research with animals, organized a symposium on reducing regulatory burden, and wrote letters and comments on various animal research issues. Gaylen Edwards chaired the ACE Committee through the end of 2015. I assumed the role of Chair on January 1, 2016.

ACE Committee meetings

At its fall 2015 meeting, the ACE Committee discussed plans for its EB 2016 symposium and outlined points to address in a letter to AAAS and Science concerning the tone of Science’s recent coverage of animal research issues. After our business meeting, we went to Capitol Hill. ACE Committee members met with legislators and staff from 16 Congressional offices representing Missouri, Florida, North Carolina, Indiana, Georgia, New Jersey, Oregon, Mississippi, and Texas. In our meetings we underscored the importance of animal research; explained scientists’ commitment to humane treatment of animals; and described the deleterious impact of burdensome regulations as well as our concern about having access to rapid and humane transportation for research animals.

When the ACE Committee met at EB 2016, we discussed priorities for the coming year. Because this is an election year, we will not go to Capitol Hill this fall. Rather, we will use our fall meeting for in-depth consideration of several topics of interest. The committee also suggested a number of questions that I have agreed to raise with OLAW and USDA about how these agencies are interpreting their oversight requirements.

2015-2016 ACE Committee Activities

EB 2016 symposium: The ACE Committee sponsored a symposium at EB 2016 entitled “Having Trouble With your IACUC?” The focus was ways to seek changes to burdensome institutional oversight policies. In my introduction, I pointed out which federal laws and regulations most frequently cause confusion for IACUCs. Anthony Comuzzie (Texas Biomedical Research Institute) focused on ways IACUCs can improve their efficiency, such as by recruiting engaged members and reviewing their policies. J.R. Haywood (Michigan State University) reviewed the highlights of reports on reducing regulatory burden published in recent years by the National Science Board and the National Academy of Sciences. He also suggested one approach IACUCs can use to rein in self-imposed burden. Barbara Hansen (University of South Florida) identified various sources of self-imposed burden and offered suggestions on what institutions should do to resolve disagreements between principal investigators and IACUCs. Linda Yang of the APS Office of Science Policy has created a web page (http://www.the-aps.org/mm/SciencePolicy/AnimalResearch/Regulatory-Burden) with links to these presentations and related materials about reducing regulatory burden.

Chapter Advocacy Outreach: In 2016 the APS will sponsor three Advocacy Outreach speakers at Chapter meetings. This is part of a program established in 2013 to offer advocacy training outside of the EB meeting. An overview of the program with instructions on requesting a speaker is provided annually to the Chapters. Chapters’ requests for speakers are honored on a first-come, first-served basis, with preference given to those that have not had a speaker recently. The talks scheduled for 2016 are:

- “Research Advocacy: Difficult Topics-Animals in Research” (Indiana Physiological Society)
  Speaker: Alicia Schiller
- “Animal Data Reproducibility” (Nebraska Physiological Society)
Speaker: Gaylen Edwards

- "Advocacy for Science: Making a Compelling and Understandable Case" (Iowa Physiological Society)

Speaker: Kevin Kregel

**Rigor and Reproducibility:** Galen Edwards, who preceded me as ACE Chair, gave a keynote address on “Reproducibility in Research: Redundancy or Requirement” at the Scientists Center for Animal Welfare (SCAW) winter 2015 conference. In his talk, he identified factors that can undermine the reproducibility of animal studies and discussed the role of veterinarians and animal care staff in addressing them. A pdf of his presentation is available upon request from the Office of Science Policy.

**Ketamine:** In 2015, the APS submitted a statement opposing a proposal before the World Health Organization (WHO) to classify ketamine as a drug with significant potential for abuse and to place it under international controls. Our statement objected on the grounds that the proposed level of regulation would have deleterious effects on clinical and research settings in both human and veterinary medicine. WHO ultimately rejected the proposal to restrict access to ketamine.

**Attachment:** APS statement opposing international scheduling of ketamine Oct. 14, 2015

**Science coverage of animal research:** Last fall in response to the troubling tone of several articles about animal research issues, the ACE Committee drafted a letter that APS President Patricia Molina sent to AAAS CEO Rush Holt, *Science* Editor-in-Chief Marcia McNutt, and *Science* news editor Tim Appenzeller. Since then it was announced that McNutt would leave *Science* to become the President of the National Academy of Sciences, and on May 25, it was announced that former NIGMS Director Jeremy Berg (currently at the University of Pittsburgh) would succeed McNutt as Editor-in-Chief of *Science*.

**Responding to Lab Animal commentaries:** *Lab Animal* magazine publishes a monthly column called Protocol Review. This column presents a scenario that might come before an IACUC and provides suggestions from several IACUC administrators, and researchers about how the committee should deal with the situation. ACE Committee member Sonnet Jonker of the Oregon Health & Science University expressed concerns about the responses to the scenario in the February 2016 column, which involved an investigator who resisted switching from open to laparoscopic cholecystectomies for his research on dietary cholesterol metabolism in owl monkeys. Alice Ra’anan worked with Jonker to formulate her concerns into a letter to the editor that was published in the May issue of *Lab Animal*.

**Santa Cruz Biotechnology settles with USDA:** On May 19, 2016, after nearly 4 years spent contesting USDA allegations of serious Animal Welfare Act (AWA) violations, antibody producer Santa Cruz Biotechnology (SCBT) agreed to settle its case with the USDA. SCBT neither admitted nor denied the violations, but it agreed to pay a record $3.5 million fine. It also agreed that it would stop producing and selling antibodies made from the blood and serum of AWA-regulated species such as goats and rabbits. An article summarizing the case against SCBT was published in *The Physiologist* in January, 2016. A year and a half earlier, on July 11, 2014, APS President David Pollock wrote a letter urging SCBT President John Stephenson to bring his company’s facilities into compliance with the AWA.

**Future activities:**

**Fall meeting:** The ACE Committee will meet October 18-19, 2016.

**NIH review of nonhuman primate research:** On September 7, 2016, NIH will hold a workshop on “the oversight framework governing the use of non-human primates in NIH-funded biomedical and behavioral
research endeavors.” The workshop is a response to instructions from the House Appropriations Committee for NIH to “conduct a review of its ethical policies and processes with respect to nonhuman primate research subjects. . . . to ensure it has appropriate justification for animal research protocols.” According to NIH’s May 24, 2016 announcement of the workshop, participants “will also explore the state of the science involving non-human primates as research models and discuss the ethical principles underlying existing animal welfare regulations and policies.” The announcement went on to say that “NIH is committed to ensuring that research with non-human primates can continue responsibly as we move forward in advancing our mission to seek fundamental knowledge and enhance health outcomes.”

**OLAW and USDA oversight:** I am preparing a letter to OLAW and USDA with a number of questions about their interpretations of certain regulatory requirements.

**Support for research animal transportation:** Committee members are being encouraged to ask their institutions to adopt statements affirming the importance of research with animals and expressing support for commercial carriers that provide humane and rapid transportation of research animals.

Respectfully submitted,

Jeff Henegar, PhD, Chair
Animal Care and Experimentation Committee