Written document summarizing discussion points presented to a panel composed of members from the NIH (OLAW), FDA, and USDA as part of a "Listening Tour" for the 21 Century Cures Act on January 9, 2018 in Washington DC.

Submitted by Stuart Leland, DVM, DACLAM

Good afternoon and thank-you for the opportunity to present to this Panel. My name is Stuart Leland and I am the Director of Research Integrity and Assurance at Princeton University. My office oversees research compliance for a wide range of research activities at the University including animal, human, work with biohazardous agents, and conflict of interest. Today I am speaking to you in my capacity as President of the American College of Laboratory Animal Medicine. We are a group of approximately 1000 veterinarians who have received specialty training in laboratory animal medicine. As such, we have training and experience that allows us to speak on behalf of animal welfare, research design and methodology, animal care, facilities design, and regulatory oversight. I bring this to your attention because members of our specialty college are uniquely qualified to comment on regulatory changes under consideration by the Research Policy Board and I am here to request a seat at the table.

We are where the rubber meets the road because it is the laboratory animal veterinarian who typically reads and interprets the regulation and develops programs at our institutions which are then scrutinized by the research community and regulators during inspections and site visits. To my knowledge, nobody has more training and on-the-job experience to understand the nuanced effects of regulatory language and their downstream effects. Please consider appointing veterinarians who are certified as laboratory animal veterinarians to sit on the Research Policy Board or any other subcommittee under consideration to develop or modify regulatory language or policy.

The 2nd area that I would like to explore with the Panel is to give consideration to a risk-based approach to animal welfare regulations modeled after the human research protections and the Common Rule. Not only is the Common Rule adopted by 18 different federal agencies – a model mentioned by other research advocates in this room – to reduce redundant and inconsistent promulgation, but the Common Rule describes in detail types of research that are exempt from further regulatory oversight as well as research that can be approved in an expedited manner such as by a single board member or administratively. This is accomplished by defining terms such as "human subject" and "research" and then only regulating those activities that fall under the definition of both "human subject" and "research." For example, research conducted in established or commonly accepted educational settings, involving normal educations practices, may be considered exempt from federal oversight.

Currently, the animal welfare regulations do not distinguish between animals used for research and animals used for education or training purposes. Thus, the current regulations do not reflect the breadth or diversity of today's complex research and training environment using animals. And so I will leave you with a number of challenges to consider as you ponder revisions to the Animal Welfare Act and the Health Research Extension Act.

Many people are advocating that we change the definition of animal to include all vertebrate animals, and even some invertebrate species. I would challenge the Panel that as part of the definition of animal we exclude specimens obtained from dead animals. Biospecimens that are not identifiable are excluded from the definition of "human subject" in the Common Rule.

Can we define “research” and differentiate animals that are used for research from those that are used for education or training purposes? Once this is done, could we consider different levels of regulatory oversight for each of the different uses of animals? As I mentioned, research conducted in established or commonly accepted educational settings are exempt from federal oversight. In addition, activities that are designed to develop or contribute to organizational knowledge, such as to improve an organization, a department, or are done for quality assurance or training purposes are not considered human subjects research.

Adopting this risk-based paradigm, some animal use might be exempt from regulatory oversight while other animal use might qualify for expedited review, allowing a single IACUC member or an administrator to review and approve the proposal. Such changes would allow organizations to focus their efforts on research that causes pain and distress and therefore demands the most attention from a moral and ethical perspective.

If such a balance could be found, I think it could result in a significant reduction in administrative burden for investigators while focusing efforts on those areas that need it most. Such a balance will help to maintain the integrity and credibility of research, which is one of the main goals behind the 21st Century Cures Act.