THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

August 21, 2015

Response of the American Association of Immunologists (AAI) to the USDA Notice of Petition: Petition to Amend the Reporting Requirements for Research Facilities Under the Animal Welfare Act Regulations
(https://www.federalregister.gov/articles/2015/06/24/2015-15499/petition-to-amend-the-reporting-requirements-for-research-facilities-under-the-animal-welfare-act)

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The American Association of Immunologists (AAI), the largest professional association of immunologists in the world, appreciates this opportunity to submit comments in response to a petition by the National Anti-Vivisection Society (NAVS) seeking certain amendments to the Animal Welfare Act (AWA) regulations.

AAI strongly supports the humane care and use of all research animals. Many of our members depend on the use of animals in their research, and therefore are concerned about their care and use. Many AAI members, including those who are veterinary immunologists, spend their working lives using immunologic discoveries to improve the health and well-being of companion animals and livestock.

AAI believes that any changes to the AWA regulations should benefit research animals or advance research. Rather than achieving these objectives, the petition's suggested changes would increase both burden and costs. Because administrative and regulatory burden are significant barriers to the productivity and efficiency of scientific researchers, AAI opposes any changes that would increase this burden without providing tangible benefit to animal welfare. Our responses to APHIS's questions are below:

1. Should APHIS amend AWRs to require research facilities that use animals for teaching, testing, and experimentation to provide specific information about how regulated animals are used (for example, for safety testing, teaching purposes, or disease research)? Would reporting this information improve animal welfare? If so, how?

APHIS should not amend the animal welfare regulations (AWRs) to mandate reporting on the specific uses of research animals. Protocols, procedures, and experiments that will be performed on animals covered by the AWA are reviewed and approved by an Institutional Animal Care and

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Use Committee (IACUC) prior to implementation. Review by an IACUC, and communication between the investigator and the IACUC, already ensure animal welfare under the teaching or experimental conditions. The submitted petition does not specify how its requests would improve upon these standards. Reporting on a specific procedure on, or location of, an individual animal will not improve the animal's welfare.

2. If research facilities were required to report the purposes of their animal research activities, what types of information should be provided, and why?

The petition does not explain how additional reporting on the purpose of research activities will benefit the research animals. AAI believes that these reporting requirements will, however, clearly increase the administrative burden on and cost to research facilities, researchers, and APHIS. If additional requirements were to be imposed, AAI recommends that the classification of research and experiment type should be very broad, since some research projects test multiple scientific aspects and use some animals in multiple experiments (often to reduce the number of animals used).

3. What might be the effects, if any, on research facilities if they are required to collect and report this additional information?

If new collection and reporting requirements were implemented, both APHIS and research facilities would experience (potentially significantly) increased administrative burden. First, APHIS would have to create standardized categories (because each research facility may categorize similar techniques differently) and enforce their use. Second, research facilities would have to implement new tracking mechanisms to adopt the new federal categorization. Research facilities would also need to develop tools to properly report research protocols and techniques, while also accounting for overlap in experimental output and the use of some animals for multiple purposes. Additionally, the cost of personnel and resources needed to make these changes would detract from the research itself; creating further hardship at a time when budgets are tight.

Further, the NAVS petition indicated that it was seeking this additional information so that "other animal welfare groups" can more accurately "target" institutions and investigators that use animals in research. This rationale is of great concern to AAI. Animal rights organizations have a long history of targeting researchers and institutions, with the goal of harming them or intimidating them into ending the use of animals in biomedical research. In addition, some animal rights organizations have broken into, and released animals from, research facilities, potentially causing great harm to these animals, which are domesticated and therefore have little chance for survival in the wild. Therefore, while providing this additional location information would not improve the welfare of the animals being used in these studies, it could be detrimental or even dangerous to individual investigators, institutions, or animals, and impede or delay important research.

4. Does the annual reporting form currently required to be used by research facilities capture sufficient information? If not, what information is missing?

Currently, research facilities must report the number of each animal species used and categorize the type of procedure performed based on the potential pain or distress that the animal experiences. This information is sufficient to determine if the facility has complied with the approved procedures, and additional information, such as location or origination of the animal, will not provide additional benefits to the animal's welfare.

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