



THE AMERICAN ASSOCIATION OF
IMMUNOLOGISTS

May 28, 2015

Response of the American Association of Immunologists to the USDA “Petition To Define Alternatives to Procedures That May Cause Pain or Distress and To Establish Standards Regarding Consideration of These Alternatives”

<https://www.federalregister.gov/articles/2015/03/30/2015-07221/petition-to-define-alternatives-to-procedures-that-may-cause-pain-or-distress-and-to-establish>

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The American Association of Immunologists (AAI), the largest professional association of immunologists in the world, representing more than 7,600 basic and clinical immunologists, appreciates this opportunity to submit comments. In their research, AAI members depend on animals, and therefore are deeply interested in matters governing their care and use. AAI strongly supports the humane care and use of all research animals; many of our members - including those who are veterinary immunologists - are dedicated to using immunologic discoveries to improve the lives and health of companion animals and livestock, and to prevent the transmission of zoonotic diseases.

While AAI is fully committed to the humane treatment of research animals, we do not believe that the changes proposed in the petition would improve their welfare. Instead, these suggested changes would increase administrative burden on the collaborative efforts between researchers and the members of the Institutional Animal Care and Use Committees (IACUC). Because administrative and regulatory burden is a significant barrier to the productivity and efficiency of the nation’s scientific researchers, AAI opposes any changes that would increase this burden without providing tangible benefit to animal welfare.

In addition to our own comments (below, with responses numbered per the Notice of Petition), AAI recommends to USDA the comments submitted by the Federation of American Societies for Experimental Biology (FASEB), of which AAI is a founding member, and the American Physiological Society (APS).

1. Should APHIS establish regulatory standards for consideration of alternatives to procedures that may cause more than momentary or slight pain or distress to animals?

APHIS should not establish regulatory standards for consideration of alternatives. The evaluation of whether alternatives need to be, and have been, thoroughly considered is the role of the IACUC (see Policy #12 of the *Animal Care Resource Guide Policies*), and there is no need to add additional regulatory oversight. Definitions and examples of what may constitute “painful procedures” and considerations of alternative procedures are sufficiently clear in the APHIS *Animal Care Resource Guide Policies* (Policy #11) to provide the needed guidance to IACUC and the investigators. The areas of research that utilize animal models are broad and the procedures used are evolving continuously; standardization of alternatives for each procedure and in each animal model is unrealistic and of questionable value.

2. What constitutes an alternative to a procedure that may cause more than momentary or slight pain or distress? If we amend the AWA regulations to define the term *alternative*, what definition should we use?

The term “alternative” is not ambiguous. The definition of “alternative” is specified in the *Animal Care Resource Guide Policies*, Policy #12 as, “methods that use non-animal systems or less sentient animal species to partially or fully replace animals ..., methods that reduce the number of animals to the minimum required to obtain scientifically valid data, and methods that refine animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being...” Therefore, AAI is opposed to adding yet another definition of “alternative” to the AWA, since it is unnecessary and potentially confusing.

3. What constitutes a thorough consideration of alternatives? Does this differ depending on the nature of the research conducted? If so, how?

Investigators already must provide a rationale for why they are using their particular animal model and why alternatives, including non-animal options, were deemed inadequate for answering the experimental question. This consideration of alternatives typically involves a combination of factors: 1) reviewing the investigator’s expertise, 2) searching the literature for similar experimental situations, and 3) considering information learned from discussions with colleagues and at scientific meetings. Flexible consideration of these factors, the balance of which will differ depending on the nature of the research being conducted, is already standard procedure.

4. Who should make a determination regarding the thoroughness of a primary investigator's consideration of alternatives: The IACUC for a facility, APHIS, or both parties?

The IACUC should continue to determine whether a principal investigator has thoroughly considered available alternatives. The IACUC has the local expertise to be most familiar with the evolving procedures used by researchers at its institution, and is therefore best suited to make the most informed decisions on the consideration of alternatives as part of its current mission. If APHIS were to become involved in the determination of whether every investigator at every institution had thoroughly considered all alternatives, research would grind to a halt as APHIS would be increasingly overwhelmed by the volume of protocol applications (which it would

likely have to handle without any increased budget or additional staff). If both APHIS and the IACUC had a role in making this determination, it would substantially increase the burden for all parties, including investigators, without a tangible improvement in animal welfare.

5. If the IACUC and APHIS should jointly make a determination, which responsibilities should fall to APHIS and which to the IACUC in terms of evaluating thoroughness?

AAI does not support a role for APHIS in the determination process. We firmly believe that such responsibilities should remain with the IACUC.

6. What documentation should the primary investigator provide to demonstrate that he or she has done a thorough consideration of alternatives?

AAI supports the suggestion made by FASEB that investigators should provide a narrative that evaluates the proposed research in terms of replacement, refinement, and reduction (The 3Rs).