



THE AMERICAN ASSOCIATION OF
IMMUNOLOGISTS

**Response of the American Association of Immunologists (AAI) to the
NIH Request for Information: Animal Care and Use in Research**
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-152.html>

June 12, 2018

*Submitted on behalf of AAI by Lauren G. Gross, J.D.,
Director of AAI Public Policy and Government Affairs*

Input is sought on the following proposed actions:

1. Allow investigators to submit protocols for continuing review using a risk-based methodology.

The American Association of Immunologists (AAI) is the nation's largest professional society of research scientists and physicians who study the immune system. Many of the comments AAI is submitting today endorse or incorporate, in whole or in part, comments already submitted by the Federation of American Societies for Experimental Biology (FASEB), of which AAI is a founding member.

AAI agrees that investigators should be allowed to submit protocols for continuing review using a risk-based methodology, and believes that this methodology should be used for both new and continuing protocols. However, NIH would need to provide a clear definition of "risk-based methodology" and ensure that the implementation process would not add more burden to the Institutional Animal Care and Use Committees (IACUCs). Studies that are low-risk, minimally invasive, or non-invasive should not require full IACUC review; instead, these types of studies should use a designated member review (DMR) or an expedited review.

2. Allow annual reporting to OLAW and USDA on the same reporting schedule and as a single report through a shared portal.

AAI agrees that annual reporting to OLAW and USDA on the same reporting schedule and as a single report through a shared portal should be allowed. To reduce burden, however, it would be important to ensure that the content required is coordinated and streamlined, to avoid the need for an even more comprehensive report to satisfy both organizations.

3. Harmonize the guidance from NIH and USDA to reduce duplicative considerations of alternatives to painful and distressful procedures.

AAI agrees that the guidance from NIH and USDA to reduce duplicative considerations of alternatives to painful and distressful procedures should be harmonized. Further, the revised guidance should not require keyword/literature searches.

4. Provide a minimum 60-day comment period for new OLAW policy guidance.

AAI agrees that a minimum 60-day comment period for new OLAW policy guidance is needed. In fact, AAI believes that a minimum 90-day comment period would be most beneficial, as this would provide sufficient time for the scientific community to provide thoughtful and comprehensive input.

5. Other approaches not previously mentioned.

AAI has several recommendations to reduce unnecessary burden that were not mentioned above:

- Change the time frame for IACUC review from three years to five years to coincide with the time frame of most R01 grants. The current three year limit to IACUC protocols is arbitrary; unless there is a scientific justification for the use of three years, a five year time frame would be more practical and would help to reduce unnecessary burden.
- Reduce the requirement for biannual IACUC inspection to annual inspection.
- Work with the community to address any increased burden caused by differing NIH and USDA requirements for protocol review. Although NIH does not, appropriately, require annual review, some institutions use the annual review required by USDA for all species (including for non-USDA-covered species such as laboratory rats and mice), potentially causing unnecessary additional burden.

Additionally, AAI agrees with the recommendations suggested by FASEB in its comments:

- “NIH should eliminate the requirement for verification of protocol and grant congruency in NIH Grants Policy 4.1.1.2 to allow for reasonable advances, discoveries, and other developments in the overall research objectives.” In the view of AAI, verification of congruency after the IACUC has approved the protocol causes unnecessary duplication of effort.
- “OLAW should revise FAQ C7 and PHS Policy IV.B.3.c to ensure that IACUC approved alternative strategies from ‘should’ statements in *the Guide for the Care and Use of Laboratory Animals (Guide)* are not deemed departures or deviations and are not required to be included in the semiannual report to the Institutional Official.”
- “Amend the third bullet in section 8.1.2.5 of NIH Grants Policy to read ‘Change from the approved use of live vertebrate animals that would result in an increased risk.’”

- “Revise §2.31(c)(3) of the AWR to state: “The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution’s programs and facilities that includes all members wishing to participate in the process. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.””
- “Revise the NIH guidance in NOT-OD-05-034 regarding prompt reporting to include only those incidents that jeopardized the health or well-being of animals.”

Input is sought on whether the following tools or resources are or would be helpful for reducing burden on investigators:

1. Encourage the use of sections of the AAALAC International program description in applicable parts of the OLAW Animal Welfare Assurance, for institutions accredited by AAALAC International.

AAI agrees that OLAW should consider AAALAC International guidance in an effort to streamline the OLAW Animal Welfare Assurance.

2. Encourage the use of the Federal Demonstration Partnership (FDP) Compliance Unit Standard Procedures (CUSP) as a repository of best practices for standard procedures used for research with animals.

Because this program is only in the pilot testing phase, AAI suggests that a decision about this should only be made after testing is complete and its impact is fully reviewed.

3. Encourage the use of the IACUC Administrators Association repository of best practices by IACUCs.

Because much of the information regarding the IACUC Administrators Association best practices is currently behind a members-only paywall, AAI does not believe that encouraging its use would reduce burden.

Furthermore, a potential problem with the use of these best practices is that IACUCs sometimes consider the requirements for USDA-covered species as “best practices” and therefore could require the use of those practices even for non-USDA-covered species. Therefore, NIH/OLAW would need to clarify that USDA-mandated practices are not considered “best practices” for non-USDA-covered species.

4. Encourage the use of new or existing tools to streamline protocol review through use of designated member review (DMR), DMR subsequent to full committee review, and/or Veterinary Verification and Consultation.

AAI believes that it would be helpful to streamline protocol review through use of DMR. As stated above (comment A, proposed action #1), a risk-based approach to protocol

review should be used so that studies that are low-risk, minimally invasive, or non-invasive would not require a full IACUC review and instead use a DMR or expedited review.

5. Expanded IACUC training activities that focus on reducing burden on investigators.

AAI does not agree that IACUC training activities that focus on reducing burden should be expanded. AAI believes that this expanded training would, in fact, increase burden on investigators.