

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 annual reporting 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.

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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.