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February 20, 2019

Patricia Brown, VMD, MS
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500
Bethesda, MD 20892

Re: NOT-OD-19-028 "Request for Information (RFI): Input on Draft Report from Working Group on Reducing Administrative Burden to Researchers for Animal Care and Use in Research"

Dear Dr. Brown:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the NIH's request for information regarding the draft report on reducing administrative burden to researchers for animal care and use in research. The AAMC is a not-for-profit association representing all 152 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 173,000 faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC commends the formation of the Working Group by NIH OLAW, USDA, and FDA to take steps to reduce overlapping regulations and policies in animal care and use and improve coordination between agencies, as directed by Section 2034(d) of the 21st Century Cures Act (P.L. 114-255). We are also encouraged by the thoughtful review of the responses, including from the AAMC,[1] to the previous request for information, as well as the 2017 joint associations' report on reforming animal research regulations.[2] The Working Group led by NIH OLAW was clearly diligent in its collection and evaluation of public and stakeholder input, and we are greatly encouraged by many of the recommendations in the Working Group's Draft Report. The AAMC continues to believe that information sought in the initial Request for Information, and subsequent inter-agency deliberation, has been narrowly focused, and not fully commensurate with the 21st Century Cures Act's broad vision for regulatory streamlining. But the "recommended steps" in the Draft Report, if given a defined timeline and plan for implementation, represent genuine progress.

A case in point is the Working Group's recommendation for OLAW to permit inclusion of elements of the AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care international) program description in the Animal Welfare Assurance. The research community views AAALAC voluntary accreditation as the gold standard for the humane treatment of animals used in

[1] https://www.aamc.org/download/489596/data/nihrfi-animalresearch.pdf
[2] http://www.faseb.org/Portals/2/PDFs/opa/2017/FASEB-Animal-Regulatory-Report-October2017.pdf

scientific research. In supporting this recommendation, we appreciate that a federal oversight agency and an independent accrediting agency are distinctly different entities and not to be confounded. But the information and practices generated by the accreditation process are demonstrably useful to factor in the federal assurance process. We therefore strongly support the OLAW's "plan to coordinate with AAALAC about options for harmonizing documents" and would encourage that the Working Group's final report be more specific about a scope and timeline for these recommendations.

The AAMC also supports the Working Group's key recommendations on inspections and protocol review but urges that these reforms go further. We welcome providing IACUCs with additional guidance on the broader use of Designated Member Review (DMR), as opposed to full committee review, as a step toward a risk-based review process, parallel to that employed for research with human subjects. We support the proposal for USDA rulemaking to replace the requirement for "continuing reviews" with a requirement to conduct a three-year de novo review of activities (Subchapter A-Animal Welfare Act, Section 2.31(d)(5), provided that "de novo" does not imply rewriting existing protocols.

The AAMC agrees with these further recommendations in the Draft Report:

- The USDA to pursue regulatory change (Section 2.30(a)(1) of the Animal Welfare Act) that eliminates the requirement to renew registration every three years.

- NIH OLAW to reevaluate the provision of the grant number with non-compliance reports, along with other review of reporting requirements and timeframes. In fact, the AAMC would urge commitment to a specific time frame and intended outcome for this review.

- A 60-day comment period for NIH OLAW "significant policy guidance" on new interpretations of PHS Policy, the National Academies' Guide for the Care and Use of Laboratory Animals, or the AVMA (American Veterinary Medical Association) Guidelines for the Euthanasia of Animals. The AAMC asks that this comment period be extended to all new guidance, as administrative burden often arise from seemingly minor policy changes, and that all such guidance be posted.

- NIH OLAW and USDA to promote proactive sharing of best practices through the Federal Demonstration Partnership to create Compliance Unite Standard Procedures (CUSP), and to offer resources for such sharing.

The AAMC strongly supports the Working Group's proposal for coordination with VA and DOD review. While the draft notes those agencies are outside the scope of the provision (2034(d)) of the 21st Century Cures Act, we believe this is exactly the type of initiative that is in keeping with the Act's spirit to unify and make consistent the application of regulations across research.

The National Academies *Guide for the Care and Use of Laboratory Animals* provides explicit recognition of alternative approaches and other language that support the interpretation that such differing or alternative approaches are likely events. The AAMC therefore disagrees with the Working Group's interpretation that IACUC approved deviations from "should" statements in the

Guide should be exceptional. The Working Group asserts that such a change (from exceptional to likely) "would negatively impact animal welfare." If that assertion remains in the final report, evidence should be provided.

The AAMC also disagrees with the contention that research animals' needs for around-the-clock care, whether they are or not yet involved in a research protocol, requires substantively different forms of oversight than a unified, risk-based standard similar to the protection of human subjects. The need for such continuous care, and institutional commitment to it, in many ways would make centralized oversight more effective, not less.

As each agency proceeds with the plans outlined in this report, engaging individuals involved with oversight responsibility at the institutional level such as administrators, IACUC members, veterinarians and investigators would be helpful to overcome potential obstacles and ensure burden reduction. The AAMC supports establishment of an external advisory group composed of members with institutional expertise which meets on a regular and continuous basis to provide information to the agencies.

The AAMC hopes that a final report would explicitly commit to eliminate requirements for literature searches as demonstration of compliance in seeking alternatives to the use of animals in a research project.

In closing, we note that the Working Group's conclusion to the section summarizing steps to reduce duplicative requirements and to improve coordination (page eight of the Draft Report) emphasizes the importance of striking a "reasonable balance" between advancing scientific knowledge and protecting the welfare of animals used in research. The text then allows, "however, certain existing requirements consume researcher time and are due for review." The AAMC believes more emphatically that the advancement of scientific and medical knowledge depends on the appropriate care and welfare of the animals used in research. Also, overlapping, duplicative, or unnecessary requirements not only cost researchers time, but detract energy and resources which can be better employed protecting the welfare of the animals, and ensuring that animals are treated appropriately. The Association considers the Draft Report to make significant progress in this direction, although more will be needed, and appreciate again the diligence with which the Working Group has sought and incorporated diverse public and stakeholder input.

The AAMC looks forward to staying engaged with the NIH, USDA, and FDA on this issue, and would additionally be happy to facilitate engagement with our member institutions. For further questions or discussion, please contact me or my colleagues, Stephen Heinig, Director of Science Policy, at sheinig@aamc.org, or Anurupa Dev, PhD., Lead Specialist, Science Policy, at adev@aamc.org.

Sincerely,

Ross E. McKinney, Jr., MD
Chief Scientific Officer