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June 7, 2018

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Attn: Patricia Brown, VMD, MS
olaw@nih.gov

RE: NIH Request for Information: Animal Care and Use in Research (NOT-OD-18-152)

Dear Dr. Brown:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide information on this request. The AAMC is a not-for-profit association representing all 151 accredited US medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Our comments here derive in part from the report, “Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden, 2017,” (“Associations’ Workshop Report”) developed by AAMC, the Federation of American Societies for Experimental Biology the Council on Governmental Relations, and the National Association for Biomedical Research, and cited in the preamble to the RFI notice.¹ Each of these organizations, as well as Public Responsibility in Medicine & Research (PRIM&R), has also submitted extensive comments responding to this RFI and we commend those comments to OLAW’s attention.

Comment A: Input sought on proposed actions:

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

The AAMC supports relying on risk-based approaches to structuring oversight and enforcement. A comprehensive revision of the animal welfare regulations with this approach in mind could result in allowing investigators to submit research protocols for continuing review based on risk. The goal for regulatory reform in this area is to optimize the effectiveness of policies, regulations and oversight in protecting the welfare of the animals used in biomedical research. The AAMC is focused on reducing regulations not for the sole purpose of reducing burden on institutions, but ensuring that limited resources, including the time of faculty and personnel, are directed most effectively to the protection of, and care for, animals used in research. Redundant, unnecessary, or conflicting regulations and responsibilities divert resources from that mission.

The Associations’ Workshop Report called specifically for greater oversight in areas with a higher risk to research animals, consistent with the regulatory framework for protection of

¹ The Associations’ Workshop Report is available at <https://www.aamc.org/download/485962/data/reforminganimalresearchregulations.pdf>.

human subjects in research. Public Health Service Policy IV.C.2 allows for review of proposed research projects through either full committee or designated member review, if no committee members object. This risk-based approach is more administratively efficient than the current animal regulatory framework, while maintaining necessary protections. As recommended in the Associations' Workshop Report, OLAW could amend the protocol review requirement to define types of studies involving low-risk, noninvasive, or minimally invasive procedures. These studies could then be deemed exempt from full Institutional Animal Care and Use Committee (IACUC) consideration or eligible for administrative or single member (expedited) review, without concurrence by the full IACUC. The AAMC also expects that OLAW would collaborate with the US Department of Agriculture (USDA) in identification of low risk areas of research, relevant to comments below.

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

The AAMC supports the use of a unified reporting schedule and single, shared portal and notes that this single change, while useful, should be implemented as part of a broader review and harmonization of relevant policies and regulations across multiple agencies, including NIH/OLAW and the USDA. A comprehensive assessment and revision is both directed by the 21st Century Cures Act ("the Cures Act"), and is consistent with the National Academies' recommendations for addressing unnecessary regulatory burden in animal research. The Academies called for a unified reporting schedule across all agencies supporting research with animals. The action proposed here around a unified schedule and shared portal is a welcome, but relatively minor change in the spectrum of changes NIH, OLAW, and USDA could implement.

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

The AAMC vigorously supports efforts to harmonize NIH and USDA requirements on the use of animals in research, consistent with the Associations' Workshop Report, including both regulations and guidance documents. A specific example would be to eliminate USDA's policy requiring a literature search for alternatives to potentially painful procedures. The pro-forma literature search does not serve the ultimate goal of minimizing pain and distress for animals used in research. This goal is better served by permitting investigators to concentrate on making certain the justification section of a research proposal is clear and can be adequately reviewed by the IACUC. A further area for harmonization would be to reduce or consolidate requirements for on-site inspections, and adjust the frequency of inspections to fit factors specific to the facility and the research.

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

The Associations' Workshop Report recommends requiring at least a 60-day comment period on the merits and impact of any proposed policies, guidance documents, FAQs, or interpretive rules before they are issued, and the AAMC welcomes the proposal to make this comment period a requirement. Moreover, the final policies and guidance issued by OLAW should reflect how the input from the regulated community was considered and incorporated in these policies. There is

also a caveat in this recommendation, that the NIH and the research community respect and, as necessary, restore the distinction between regulation and policy. Guidance documents should state clearly that they do not carry legal or regulatory force, and should not be accompanied by a requirement to obtain agency approval for alternative methods and/or processes. As also noted in the Associations' Workshop Report, the NIH should ensure that IACUC-approved alternative strategies that are not directly aligned with "should" statements in the Guide are not deemed departures or deviations, and are not required to be included in the semiannual report to the Institutional Official. As the Associations' Workshop Report notes, such practice would be consistent with the Office of Management and Budget (OMB)'s Agency Good Guidance Practices Bulletin and would significantly reduce administrative burden without compromising animal welfare.

5. Other approaches not previously mentioned.

The AAMC is heartened to see the NIH currently reviewing its policies for the humane use and protection of animals in research and, consistent with the Associations' Workshop Report recommendations, encourages the agency to take on a more expansive and inclusive approach than is represented by the moderate changes posed by this RFI. The RFI, which could readily have asked open questions about the most impactful ways to reform animal regulations, is notably narrow in scope, raising concerns about whether the goals of 21st Century Cures will be realized.

Among other proposals made in the joint associations' working group: (1) NIH and other federal agencies involved in the review of regulations and policies for the care and use of laboratory animals mandated by the Cures Act should appoint an external advisory group of experts engaged in animal research from entities that receive federal research awards to serve as advisors. The advisory group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research. This will foster progress and impartiality in the conduct of the NIH's review, which should take into account relevant regulations, policies, and guidance, along with the recommendations of the Associations' Workshop Report and other reports that have addressed regulatory burden associated with animal research. (2) 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. (3) Revise the NIH guidance in NOT-OD-05-034 regarding prompt reporting to include only those incidents that jeopardize the health or well-being of animals.

Comment B. Input is sought on whether the following tool or resource is 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.

The AAMC supports this proposal, consistent with the Associations' Workshop Report recommendation that for Category 1 institutions, NIH "allow proof of accreditation in lieu of the detailed program description."

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.

The AAMC strongly supports this proposal. Moreover, the Association is working with research deans at member institutions on promotion of the FDP's Compliance Unit Standard Procedures and best practices, for more effective compliance and "self-regulation."

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

The AAMC strongly supports development and use of this repository.

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.

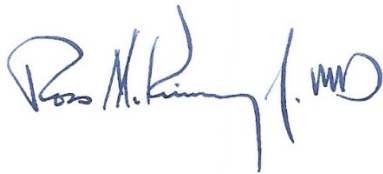
The AAMC supports this proposal.

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

The AAMC supports this proposal, provided that training is efficient and effective, and not itself the source of new compliance burden that does not effectively promote good practices.

The AAMC again appreciates the opportunity to comment to the NIH on this issue and would be happy to provide any further information. Please contact me or my colleague, Stephen Heinig, Director of Science Policy, (sheinig@aamc.org, 202-828-0488) with any questions about these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ross E. McKinney, Jr. MD". The signature is stylized and includes a circular mark at the end.

Ross E. McKinney, Jr, MD
Chief Scientific Officer

cc: Council on Governmental Relations
Federation of American Societies for Experimental Biology
National Association for Biomedical Research
Public Responsibility in Medicine & Research