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August 8, 2024

Standing Committee for the Care and Use of Animals in Research
National Academies of Science, Engineering, and Medicine
Board on Animal Health Sciences, Conservation, and Research (BAHSCR)
500 Fifth St., N.W. Washington, D.C. 20001

RE: Request for Feedback and Information on Updating the Guide for the Care and Use of Laboratory Animals

Submitted electronically via portal.

Dear Standing Committee Members,

The American Society for Pharmacology and Experimental Therapeutics (ASPET) appreciates the opportunity to provide comments on the Request for Feedback and Information on Updating the Guide for the Care and Use of Laboratory Animals. ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases. ASPET appreciates the chance to comment on the Request for Feedback regarding future updates to the Guide for the Care and Use of Laboratory Animals (Guide). We provide the following comments and suggestions to ensure the next edition of the Guide reflects the concerns and needs of its intended users, including a large portion of the ASPET membership.

The Committee should take this opportunity to simplify and clarify the language of the Guide.

Since the Guide is generally treated as a regulatory document, we recommend the Committee take this opportunity to clearly outline distinctions between mandates (i.e., legal or other statutory requirements) and recommendations as well as to ensure consistency across sections within the document to avoid confusion about the intent of the guidance. Recommendations (“should” and “may” statements) often evolve to become functionally treated as mandates (“must” statements) through local interpretation due, in part, to ambiguous language. We recommend reserving “must” (or an equivalent) for application to statutory requirements with all else being recommendations based on scientific evidence. We recommend these distinctions be explained clearly early in the text of the document.

We also recommend that the Committee clarify for animal researchers citing the Guide in manuscripts to be clear on what level of performance standards they should have conducted the research under in order to reference the Guide in their publications.

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Clarify the language regarding the role and responsibilities of the Institutional Animal Care and Use Committee (IACUC).

Since the structure and function of IACUCs can evolve over time within an institution and can differ markedly across institutions, the updated Guide should clearly define the responsibilities, roles, and structure of the IACUC, supported by reference to the relevant statutory requirements. Such clarification should 1) highlight that the focus is to be on issues directly related to animal welfare; 2) outline the scope *and limits* of the committee's charge to prevent expansion to review of secondary issues (e.g., scientific merit [which is already a key element of funding decisions], occupational health and safety review, drug procurement and storage, etc). Gradual evolution and expansion of the scope can impose duplicative review and put undue burdens on committee members, increasing workload to include topics not within their area(s) of expertise, as well as investigators (which complicates protocol preparation and inspections); and 3) explicitly discourage institutions from employing the IACUC as a catch-all regulatory committee for all matters related to animal research.

Maximize applicability and utility across the diverse array of institutions and other research units that utilize the Guide.

For the Guide to have broad applicability and utility, it should contain as part of that guidance sufficient flexibility that takes into consideration differences in the type and location of research environments (e.g., R1 academic, R3 academic, industry/CRO, etc). Institutions and other research environments have wide variance in available resources, scope and complexity of research portfolio, and funding environments. Including flexibility in the recommendations that take into account such variability will substantially add to the Guide's value and utility.

Establish a regular and predictable timeline for updates to the Guide.

As scientists, we appreciate the motivation for and need to update policies and practices with the availability of new information, and that maintaining the highest standards of animal care and welfare should be informed by contemporary, evidence-based approaches. However, changing policies and practices requires significant resource expenditure (time, money, and effort) at all levels. We strongly encourage the Committee to devise a scheme for updating the Guide, as needed, at regular intervals to avoid establishing a moving target using a standardized and transparent process that provides ample opportunity for stakeholder feedback and input, a clear strategy for how updates will be disseminated, and a reasonable and feasible timeline for implementation of changes.

Ensure updates are based on evidence-based and based on an outcome directly relevant to animal care and welfare.

We strongly recommend that changes to the Guide be based on peer-reviewed scientific evidence, demonstrates benefit to animal welfare, and considers species- and context-specific differences. All mandates and recommendations should be supported by direct and contemporary references to primary sources supporting their inclusion so that all stakeholders can understand the basis for inclusion. Further, we recommend that later updates to the Guide consist of a comprehensive literature review to incorporate advances in scientific knowledge gained since publication of the current version.

ASPET appreciates the opportunity to comment on future updates to the Guide for the Care and Use of Laboratory Animals. We acknowledge the significant task of revising such an important document and welcome opportunities to help advance our mutual goal of promoting humane animal care and use.

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