

COGR COUNCIL ON GOVERNMENTAL RELATIONS  
AAU ASSOCIATION OF AMERICAN UNIVERSITIES  
AAMC ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Patricia Brown, Director  
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SUBJECT: Proposed Adoption and Implementation of the Guide for the Care and Use of Laboratory Animals: Eighth Edition (NOT-OD-11-042, 056, 066)

Dear Dr. Brown:

The Council on Governmental Relations (COGR) is an association of over 180 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. The Association of American Universities (AAU) represents 61 leading public and private U.S. research institutions. AAU focuses on issues important to research intensive universities, such as funding for research, research policy issues, and graduate education. The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 134 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 62 Department of Veterans Affairs' medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

As the principal performers of National Institutes of Health (NIH) extramural research, our member institutions base their animal care and use programs and their compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals on the National Research Council's Institute for Laboratory Animal Research (ILAR) 1996 *Guide for the Care and Use of Laboratory Animals* and, as applicable, the Animal Welfare Act. However, NIH's implementation of the new Eighth Edition of the *Guide* makes significant changes to the PHS Policy. We recommend that NIH's implementation of the *Guide for the Care and Use of Laboratory Animals* be delayed until key concerns can be addressed.

While we recognize the value of the *Guide* as the basis for evaluation of our animal care and use programs, we are concerned with NIH's proposed implementation plan. The *Guide* provides the most comprehensive consideration of the care and use of animals in research. However, we are troubled by what we perceive to be a move away from performance-based standards toward more rigid engineering standards in the new edition of the *Guide* without adequate scientific rationale. Despite ILAR's assertion that performance standards continue to serve as the basis for the Eighth Edition, we are concerned with

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a shift from guidance to requirements.

In its bulletin for *Agency Good Guidance Practices* (January 2007), the Office of Management and Budget (OMB) cautions agencies against using guidance documents as a means to implement regulatory change. OMB outlines the elements for a significant guidance document – and implementation of the Eighth Edition will have a significant impact – and states that the guidance should not include mandatory language such as “shall,” “must,” etc. ILAR recognizes the weight of its word choices but ILAR is not a Federal agency and need not address the regulatory impact of its *Guide* in the same way that NIH is directed to act by OMB.

When NIH asked the research community whether and, if necessary, how the 1996 *Guide* should be updated, the community recommended against a revision. An expert committee convened by NIH reported in November 2006 that “the Committee unanimously determined that the information provided in response to the [NIH] RFI [NOT-OD-06-011] contained no scientific evidence that would warrant revising the associated performance standards of the 1996 *Guide*.” In noting the continuing relevance of the 1996 *Guide*, the Committee reaffirmed the value of true performance-based standards used in the *Guide* for ensuring the humane care and use of animals across the PHS-supported community. The only need identified by the Committee was an update to the references included in Appendix A.

Given the research community’s view and the determination of NIH’s own expert panel that a change in the 1996 *Guide* was not necessary, and in light of the approach incorporated in the Eighth Edition that is more prescriptive and “regulatory,” we urge NIH to proceed with caution in implementing the Eighth Edition of the *Guide for the Care and Use of Laboratory Animals*.

We understand that because NIH is not the author of the Eighth Edition, editorial changes are not within NIH’s purview. However, ILAR’s use of prescriptive language that sets new requirements outweighs some real strengths in the Eighth Edition, such as the recognition that all partners in animal-based research – the investigators, the institutional official, the attending veterinarian and the Institutional Animal Use and Care Committee (IACUC) – all have important roles and responsibilities in achieving compliance. The Eighth Edition continues to refine these roles and responsibilities enabling institutions to bring the appropriate expertise and knowledge to the various tasks.

We are troubled, however, that these refinements in responsibilities require a careful and thorough review of the facilities’ standard operating procedures to ensure compliance. For example, the description of expanded roles for the IACUC in meeting its responsibilities in areas like post-approval monitoring, training of investigators, etc., may require the development of new procedures and, if necessary, new policies. These tasks will take time to complete and implement.

Of greater concern are the changes in housing and environmental engineering standards that will require a significant financial investment for many, if not most, institutions. If required to adhere to

new “minimum” standards, some institutions have estimated investments in new cages in excess of \$1.5 million to achieve compliance with the standards for their rodent breeding colonies. The introduction of more detailed standards for aquatic animals will require investments as well. Changes in environmental standards for personnel health and safety and engineering controls like emergency power, etc., have associated costs. The costs go beyond the purchasing of new equipment. In addition to such capital investments, the on-going operating costs of newly configured caging and associated changes will increase the over-all investment for most institutions. The maintenance of new caging may require additional personnel. Maintaining facilities that accommodate greater social housing or increased biosecurity can be more labor intensive. Given the current economic climate and general financial challenges faced by the research community, the funds to support these costs are not readily available and will have to be identified over time.

We recommend that NIH delay implementation of the Eighth Edition of the *Guide to the Care and Use of Laboratory Animals* until a thorough assessment of the costs can be made by NIH in collaboration with the research community. Following that assessment, a determination can be made which of the new elements incorporated into the Eighth Edition of the *Guide* will be required under PHS policy.

Furthermore, we believe that when it proceeds with the implementation of the Eighth Edition NIH must affirm its commitment to performance-based standards as the basis for the evaluation of institutional programs receiving PHS support for activities involving animals. As ILAR notes, institutions must be able to bring the extensive experience and sound judgment of their professional and scientific staff to bear on the humane use of the animals in our care. NIH should reiterate its continuing commitment to and expectation that institutions will avail themselves of the expertise and skills of their scientists and staffs.

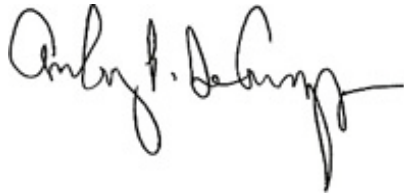
After the assessment and identification of key elements in the Eighth Edition, we propose that NIH take a different approach to implementation. Rather than setting the Eighth Edition as the basis for evaluation of compliance with the PHS Policy by March 31, 2012, we recommend that the Eighth Edition of the *Guide* serve as the basis for an institution’s plan for implementation. The institution’s plan for implementation could be expected to include a timeline with benchmarks for implementation; a timeline we are confident realistically will extend well past March 2012. Some elements, such as changes in standard operating procedures, could be completed relatively quickly. Other elements, such as the purchase of new cages may need to be phased in over time. In the latter example, it would be fiscally wise for an institution to purchase cages that meet the new requirements on a replacement schedule. In all cases, institutions will want to review the recommendations in the Eighth Edition and determine how they will meet or exceed the suggested performance-based elements.

The institutional plan can be reviewed during any inspection by the IACUC or an external evaluator or inspector. The plan should include a process for continuing review and evaluation and provide a reasonable mechanism for making adjustments to the plan based on changed or changing

circumstances. For example, an institution may reduce the number of certain types of animals in use at the facility over time. Such a change in use may allow for a reduction in the number of cages that need to be purchased to achieve compliance. The reverse circumstance would also be true; an increase in number of animals held may require an increase in the number or timing of cages purchased.

Therefore, we urge NIH to consider a different approach to the implementation of the Eighth Edition of the *Guide* that we believe would ultimately be more effective and cost efficient. NIH should conduct a thorough assessment and evaluation of the costs related to implementation; and affirm its commitment to performance-based standards in evaluating the humane use and care of animals used in PHS-supported activities by treating the Eighth Edition of the National Research Council's Institute for Laboratory Animal Research (ILAR) *Guide for the Care and Use of Laboratory Animals* as a true guide rather than a new policy or regulation. To this end, NIH should instead direct institutions to develop their own individualized plans for implementation that would be available to NIH on request.

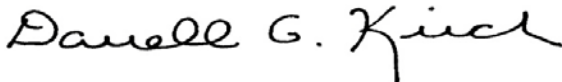
Sincerely,



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