

January 30, 2012

Francis S. Collins, MD, PhD
Director, National Institutes of Health
Building One, 126 Shannon
One Center Drive
Bethesda, MD 20892

RE: OLAW Position Statements on the Eighth Edition of the *Guide for the Care and Use of Laboratory Animals*

Sent via U.S. Mail and submitted online at the OLAW Website

Dear Dr. Collins:

The American Psychological Association (APA) submits these comments to the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) regarding its understanding of the Position Statements on the Eighth Edition of the *Guide for the Care and Use of Laboratory Animals* (*Guide*), as requested on December 1, 2011 (76 Fed. Reg. 74803). The APA Committee on Animal Research & Ethics (CARE) has reviewed the Position Statements and assessed the potential impact of these interpretations of the Public Health Service (PHS) Policy on the conduct of nonhuman animal research in psychology. As a standing committee of APA committed to the humane treatment of laboratory animals for over 85 years and representing a membership of over 154,000 researchers, educators, clinicians, consultants, and students, CARE has been involved in developing and updating guidelines for the humane care and treatment of nonhuman animals in research. Because research with laboratory animals is an integral component of the science of behavior, APA has strongly supported past efforts to improve laboratory animal welfare while ensuring that proposed policies do not compromise scientific research.

APA appreciates OLAW's efforts to address important issues raised by the research community at large during the initial comment period. As we noted then, it is not cost per se that the research community objected to, but it was increased cost in the absence of any demonstrable improvement in the welfare of laboratory animals. APA recognizes that OLAW released these position statements to clarify the use of the *Guide* in assessing compliance with PHS policies. We hope that the final position statements will provide institutions with the flexibility necessary to tailor the guidelines to their individual animal care and use programs. APA's specific comments addressing OLAW's Position Statements on the *Guide* are as follows:

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1. **Position Statement: Cost**

As OLAW noted, nearly 70% of respondents in the initial comment period raised concerns about the cost of implementing the 8th Edition of the *Guide*. Many comments noted examples of spending scarce research funds in the absence of scientific data demonstrating that the expenses would significantly improve laboratory animal welfare. APA believes that OLAW decisions related to the housing and use of nonhuman animals in PHS-funded research should be evidence-based to ensure both actual improvement in the welfare of the research animals as well as integrity of research findings.

Principle II of the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, referenced by OLAW, states, "Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society." APA agrees with this statement and further believes that consideration of costs is also of benefit to society and would therefore be congruent with Principle II. APA recommends that the position statement be revised as follows:

> Animal welfare and the integrity of research findings, rather than costs alone, should be the primary factors in decisions related to assuring compliance with the recommendations in the *Guide* in PHS-funded research. (See U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training Principle II.) Assured institutions are responsible for compliance with the *Guide*. OLAW believes compliance can be best accomplished using teamwork, professional judgment, and experience. The PHS Policy and the *Guide* define the minimum standards ("musts") and performance standards ("shoulds") that OLAW expects of Assured institutions. OLAW recognizes there are many ways to achieve humane laboratory animal care and use. An institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy as determined by OLAW. In many instances, institutions and IACUCs elect to exceed the standards. This is not required and can add expense to the program.

2. **Position Statement: Housing**

APA believes that this position statement should be revised. The position statement states, "the *Guide's* space recommendations are a starting point for addressing space needs..." APA believes the use of the phrase "starting point" in conjunction with the titles of the tables on pages 57-63, "Recommended Minimum Space," are likely to cause confusion and also imply the recommendations contained in the table are in fact minimum requirements ("must" statements). In addition, the use of the term "starting point" is inconsistent with OLAW's preceding position statement that "an institution may elect to follow a different course of action than a 'should' statement in the *Guide* if that action results in an equivalent outcome and is reviewed and approved by the IACUC." Therefore, APA recommends clarifying this position statement to read as follows:

> OLAW concurs with the recommendations of the *Guide* that performance standards are to be applied to housing issues. (See *Guide* pages 50-63.) Outcome-based performance

standards are paramount when evaluating cage or pen space for housing laboratory animals used for research, research training, and biological testing.

While the *Guide's* space recommendations are accepted reference points for addressing space needs, performance standards allow flexibility to improve laboratory animal welfare and scientific research.

An institution's laboratory animal housing practices must be species-specific, appropriate for the animals, and in compliance with all applicable federal and local regulatory requirements.

2a. Position Statement: Nonhuman Primate Housing

APA believes revisions are needed to this position statement to ensure consistency with USDA's Animal Welfare Regulations. The position statement states, "Housing of nonhuman primates in social settings (pairs or groups) is the requirement of the USDA regulations (9 CFR Ch. 1, Part 3, Subpart D)…" However, Section 3.81 of the Animal Welfare Regulations actually requires that, "The environment plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature." According to the *Federal Register* Vol. 56, No. 32 on February 15, 1991, "The regulations as proposed do not specifically call for group housing of nonhuman primates" (emphasis added). Therefore, OLAW's position statement should be revised to accurately reflect the language in the regulations. APA recommends revising the third paragraph to read as follows:

> Institutions are encouraged to consult the Animal Welfare Act and Regulations on primate housing requirements. Compliance with the USDA regulations is an absolute requirement of this [PHS] Policy. (See PHS Policy footnote 2.) Exemptions to the social housing requirement must be based on strong scientific justification approved by the IACUC or for a specific veterinary medical or behavioral reason. Lack of appropriate caging does not constitute an acceptable justification for exemption.

In addition, the last paragraph should be deleted because FAQ F14 does not accurately reflect the history that led to the current regulatory language.

2b. Position Statement: Environmental Enrichment

APA commends OLAW for addressing environmental enrichment in its position statements. We also believe that enrichment devices "…contribute to, rather than detract from, the animal's living space and need not be subtracted from the floor dimensions."

2c. Position Statement: Rodent Housing

APA believes that this position statement should be revised. The position statement states, "the *Guide's* space recommendations are a starting point for addressing space needs..." As noted above, APA believes the use of the phrase "starting point" in conjunction with the titles of the tables on pages 57-63, "Recommended Minimum Space," are likely to cause confusion and also imply the

recommendations contained in the table are in fact minimum requirements ("must" statements). In addition, the use of the term "starting point" is inconsistent with OLAW's preceding position statement that "an institution may elect to follow a different course of action than a 'should' statement in the *Guide* if that action results in an equivalent outcome and is reviewed and approved by the IACUC." Therefore, APA recommends clarifying this position statement to read as follows:

> OLAW supports the *Guide's* approach to applying performance standards to achieve specified outcomes and expects institutions to use the *Guide's* space recommendations in that process. Adjustments to recommendations for primary enclosures may be made at the institutional level by the IACUC. The IACUC should critically evaluate objective measures of outcome-based performance. The *Guide* identifies examples of performance indices to assess adequacy of housing including health, reproduction, growth, behavior, activity, and use of space.

2d. Position Statement: Rabbit Housing

APA commends OLAW for addressing this issue in its position statements.

3. Position Statement: Non-Pharmaceutical-Grade Substances

APA believes revisions are needed to the position statement addressing non-pharmaceutical-grade substances. The position statement states, "The IACUC is responsible for evaluating the potential adverse consequences of such agents when used for research." APA recommends clarifying this position statement to read as follows:

> The IACUC is responsible for evaluating the potential adverse consequences of such agents when used as medications.

The revised statement would reinforce the intent of the USDA Policy # 3 Pharmaceutical-Grade Compounds in Research, which states, "Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures." The inclusion of the words "in research" in the position statement implies that this policy extends to test articles which clearly should not be the intent.

4. Position Statement: Food and Fluid Restriction/Use of Preferred Foods

APA commends OLAW for the clarity with which it addressed this issue and for the emphasis on the use of performance standards based on the level of restriction.

5. Position Statement: Multiple Surgical Procedures

APA commends OLAW for the clarity with which it addressed this issue and for the emphasis on the use of performance standards to define the nature of the surgical procedure. The position statement addressing multiple surgical procedures, along with changes to FAQ F9, has helped to clarify this issue.

APA thanks NIH for this opportunity to share our comments on the position statements released by OLAW. We recognize the importance of the *Guide* in ensuring the humane care and treatment of nonhuman animals in research and we offer our concerns and suggestions in order to ensure that the *Guide* retains its current flexibility as a guidance document, as opposed to functioning like regulations. If you have any questions, or if we can provide any further information, please feel free to contact me at 202-336-6000, or by email at sbreckler@apa.org.

Sincerely,



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