



# FASEB

Federation of American Societies  
for Experimental Biology

## Representing Over 110,000 Researchers

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July 9, 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 and e-mail: [jgfox@mit.edu](mailto:jgfox@mit.edu) and [srodriguez@nas.edu](mailto:srodriguez@nas.edu)*

Dear Standing Committee Members,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Request for Feedback regarding future updates to the *Guide for the Care and Use of Laboratory Animals (Guide)*. As a coalition of 22 member societies representing over 110,000 researchers across a broad range of scientific disciplines, we recognize the essential role this resource plays in decision-making processes about the care and use of animals in research. More importantly, we affirm that good animal care and good science are inextricably linked. Updates to the *Guide* are crucial for ensuring research practices align with the latest data, enabling animal welfare and innovative research to advance simultaneously.

FASEB remains concerned about the lack of research investigator and Institutional Animal Care and Use Committee (IACUC) representation in the Standing Committee's planning process thus far. While we appreciate the efforts to implement an iterative approach, the process of updating the *Guide* has been largely marked by unclear, prolonged timelines and ambiguous opportunities for public engagement. Unfortunately, this has led to uneven representation of certain areas of expertise. In addition to our comments on specific sections of the *Guide* that need updating, FASEB strongly encourages prioritizing our recommendations regarding the composition of the pending consensus committee and its approach toward writing and implementing the new *Guide*, including stakeholder communication. These recommendations are intended to ensure the next edition of the *Guide* reflects the concerns and needs of its intended users.

In revising the next edition of the *Guide*, FASEB offers recommendations across three categories:

1. Animal welfare and care
2. Guide interpretation and enforcement
3. Consensus committee composition and stakeholder engagement

## **Category 1: Animal Welfare and Care**

### ***Recommendation 1: Ensure Updates to Environment, Housing, and Management (Chapter 3) are Evidence-Based, Context-Specific, and Centered on Species-Typical Behavior***

Chapter 3, which concerns animal environment, housing, and management, is one of the key areas of the *Guide* that requires review and revision. FASEB strongly recommends that future changes be based on peer-reviewed evidence that demonstrates tangible benefits to animal welfare. This includes ensuring updates align with species-typical behaviors and, where appropriate, include context-specific examples to better reflect animals' diverse behavioral repertoire.

While species-, sex-, and age-appropriate enrichment can significantly improve animal welfare by eliminating abnormal behaviors and reducing stress and aggression, reactions to certain enrichment can vary and are frequently context-specific. In some cases, enrichment may exacerbate negative behaviors and create an unsafe environment for both animals and humans. For example, one study demonstrated that male mice housed with hemp ropes hanging from the cage lid showed more aggression when frequently handled by their tail. However, when handling frequency was decreased, mice housed with hemp ropes displayed no differences in aggression compared to the control group with no hemp ropes ([Gjendal et al., 2023](#)). These and other examples underscore not only the vast range of physiological and behavioral differences within and between animals but also the importance of ensuring that updated language in the *Guide* aligns with scientific evidence and validated methods that enhance animal welfare.

Finally, as stated throughout Chapter 3, various decisions related to housing and environment are a matter of professional judgment. To prioritize the health and well-being of animals, the next *Guide* must continue emphasizing that IACUCs, Attending Veterinarians (AVs), behavioral specialists, and other animal care staff are the most knowledgeable people to make animal care decisions based on institutional and local animal needs.

## **Category 2: Guide Interpretation and Enforcement**

### ***Recommendation 1: Prioritize Performance Standards over Engineering Standards***

FASEB urges the next edition of the *Guide* to strongly emphasize performance standards rather than engineering standards. One-size-fits-all policies are ineffective and contradictory to the research community's responsibility to advance animal welfare. Furthermore, biomedical research rapidly evolves such that investigators, IACUCs, and AVs cannot reasonably anticipate all possible outcomes. By endorsing flexible approaches, institutions and research facilities can confidently rely on IACUCs, AVs, and other relevant parties while empowering these entities to use their professional judgment, particularly in situations where there is an absence of scientific data.

The precise phrasing of the *Guide*'s language is important for institutional interpretation. While FASEB appreciates the current edition stating, "*The Guide is predicated on the understanding that the exercise of professional judgment both upholds the central notion of performance standards and obviates the need for more stringent regulations*" (Preface, pg. 14), this sentiment is diminished in the subsequent main chapters. Given that many institutions are risk-averse and, therefore, interpret the *Guide* language verbatim, FASEB recommends the consensus committee emphasize the importance of performance standards *throughout* the text. This will better acknowledge that every facility is unique and remind

institutions they have the discretion to make decisions that are best for their circumstances.

### ***Recommendation 2: Harmonize “Must,” “May,” and “Should” Statements with Existing Resources***

The *Guide*'s “Must,” “May,” and “Should” statements represent one of the biggest sources of confusion for the animal research community. Many institutions over-interpret the “may” and “should” statements for fear of potential noncompliance, thus compelling IACUCs, AVs, and research investigators alike to consume a significant amount of time and resources to comply with very specific language—time that could be more effectively spent toward other critical aspects of animal care.

To promote uniformity with other respected guidelines, FASEB recommends adopting the Ag Guide's terminology—“Must,” “Should”, and “Recommend”—for the next edition. The Ag Guide's explanation for how to interpret these terms is applicable to laboratory animal programs: “**Must** indicates that the animal care and use must be as stated; **should** indicates that the animal care and use ought to be as indicated unless otherwise justified; **recommend** indicates an appropriate way of doing things but leaves room for other approaches that achieve the same result.” In contrast to the vague description for “May” statements in the current *Guide* which states, “*May* indicates a suggestion to be considered,” the Ag *Guide*'s definition of “recommend” is clear in its intent and consistent with the performance standards framework.

### ***Recommendation 3: Strengthen Language About Ad-Hoc Consultants and Include Resources/Societies that Can Facilitate Collaborations***

One key advantage of the *Guide* is its advice for IACUCs to consult with outside or “ad-hoc” expertise when necessary. While mentioned in Chapter 2 as part of the section explaining the role of the IACUC, institutions frequently overlook this capability. FASEB recommends strengthening the language about this aspect of IACUC oversight and reiterating its importance in situations where there is a lack of scientific expertise. As research advances rapidly and model systems become increasingly complex, this revision could promote greater research collaboration and address key gaps that many facilities, particularly small, limited-resource institutions, may have.

To facilitate this collaboration, FASEB encourages including tables with resources, organizations, or other guidelines for IACUCs to locate appropriate subject matter experts for certain research questions. For example, the World Aquatic Veterinary Medical Association has a “[Find a Fish Vet](#)” feature that could be instrumental in identifying experts who could assist with aquatic research questions. The Association of Avian Veterinarians has a [similar feature](#) to assist with avian studies. Consolidating these resources and including them in the *Guide* will equip IACUCs to handle a wider range of animal studies, thereby advancing animal welfare and broadening research opportunities simultaneously.

### ***Recommendation 4: Clarify the Purpose of the Guide by Distinguishing Mandatory Requirements from Performance Standards***

The primary challenge in using the *Guide* is the perception that it is a regulatory and binding document. Although the Public Health Service (PHS) Policy requires institutions to base their animal care and use programs on the *Guide* (NOT-OD-12-020), several institutions go beyond the requirements of the *Guide*. This strict application and overall reluctance from IACUCs to provide flexibility poses an immense

administrative burden for investigators, IACUCs, and other animal care staff, making it increasingly difficult to conduct research and prioritize animal welfare.

FASEB recommends the next edition of the *Guide* reaffirm its intended purpose: to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. To achieve this goal, clear and unambiguous language is essential. It may be beneficial to acknowledge the discrepancy between the *Guide*'s intent and its current interpretation and use. Going one step further, the *Guide* must clearly differentiate between mandatory requirements and performance standards, with optimal animal welfare as the ultimate goal. FASEB encourages including clear instructions that IACUCs, AVs, and animal care experts have the freedom to determine how best to achieve these goals. Such clarity may facilitate less restrictive institutional interpretation and, ultimately, enhanced animal care and use programs.

***Recommendation 5: Minimize Administrative Comments Related to IACUC Processes***

To minimize confusion for IACUCs, FASEB encourages keeping recommendations focused on animal welfare-related matters rather than administrative strategies in Chapter 2. Per federal laws and regulations, IACUCs are responsible for a broad range of oversight responsibilities. How these responsibilities are applied differs across institutions and facility types to accommodate their unique needs. As currently written, the “Post-approval Monitoring” section of Chapter 2 describes the varying approaches different institutions use to fulfill the annual review, triennial review, and inspections of animal study site requirements (pg. 34). For example, regarding annual review, the *Guide* states, “*Some institutions use the annual review as an opportunity for the investigator to submit proposed amendments for future procedures...*” While we appreciate efforts to provide examples, the current phrasing (e.g., “some institutions use...”) introduces confusion for many facilities. In some cases, institutional leadership interprets this language as the only sufficient option, creating a significant burden for IACUCs. By keeping language centered on animal welfare and reminding institutions of IACUCs’ ability to exercise professional judgment, animal care programs can operate more efficiently.

***Recommendation 6: Partner with Professional Societies to Enhance Chapter 1 with Updated Resources***

To enhance the key concepts outlined in Chapter 1 of the *Guide* and support the community’s goal of rigorous research, FASEB suggests collaborating with professional societies to compile a list of updated resources that can be integrated into the new edition. For example, the ARRIVE Guidelines can help foster improved rigor and reproducibility of animal studies by facilitating consistent and transparent reporting of animal research. Another example is the Compliance Unit Standard Procedures (CUSP) online repository which enables institutions to share and use standard animal care protocols. Considering the vast knowledge and resources accumulated since the last publication of the *Guide*, professional societies such as FASEB can assist the consensus committee in developing and maintaining a list of essential resources relevant to animal care and use.

**Category 3: Consensus Committee Composition and Stakeholder Engagement**

***Recommendation 1: The Composition of the Consensus Committee Must be Balanced and Inclusive***

It is critical to ensure the consensus committee responsible for recommending and drafting revisions to the *Guide* is representative of the broader animal research community. In reviewing the current Standing Committee, FASEB is concerned about the lack of IACUC and Institutional Officer (IO) experience, as the majority of members hold degrees in veterinary medicine. While the perspective of veterinarians (and Attending Veterinarians) is crucial for a comprehensive outlook of animal health and care, it cannot be overstated the role of IACUCs in providing oversight of all animal activities, a responsibility that routinely relies on the *Guide*. Therefore, FASEB strongly recommends that AVs, current or former IACUC members (including chairpersons), IOs, research investigators, and animal care staff be equally represented on the consensus committee.

More importantly, FASEB urges equal representation of sex, gender, race, ethnicity, career stage, animal model expertise, and institution type (small, large, private, public, commercial) on the consensus committee. While we respect the extensive experience of the current Standing Committee, 73 percent (e.g., 8 out of 11) of the members are male. Additionally, from what could be gathered from committee members' bios, there is also underrepresentation in race, ethnicity, career stage, and institution type. FASEB is concerned that this is a missed opportunity to harness the full breadth of experience and perspective of the lab animal community. Dedicated efforts are needed to recruit early career investigators, IACUC members, and veterinarians from all backgrounds and institutions, as these individuals will not only be responsible for implementing the next edition of the *Guide* but also serve as leaders for the next generation of lab animal professionals.

***Recommendation 2: Consider Establishing Subcommittees to Draft Revisions to Specific Chapters of the Guide***

Recognizing the immense scope of the *Guide*, FASEB suggests creating subcommittees comprised of experts to manage revisions of specific chapters that correspond to their expertise. This approach ensures the appropriate specialists inform the revision process. More importantly, this arrangement alleviates the workload for the consensus committee, enabling it to serve in a more “steering” capacity that can widen and diversify the expertise it can recruit for each topic. To facilitate these efforts, we encourage partnering with and soliciting feedback from professional societies such as FASEB to assist the committee in identifying key subject matter experts.

***Recommendation 3: Leverage Stakeholder Feedback During the Writing and Implementation Process***

Stakeholder engagement is central to ensuring the next edition of the *Guide* is comprehensive and accommodating to the diverse range of facilities and scenarios requiring the care and use of laboratory animals. In addition to soliciting public comments on subject matter content, FASEB strongly recommends issuing a complete updated draft of the *Guide* for public review and feedback. This is consistent with the latest iteration of the Ag Guide, which was released to the public for a 75-day comment period.

Likewise, when the next edition is finalized, we suggest issuing a draft implementation plan to facilitate awareness of key changes and planned effective dates. One strategy to consider is collaborating with the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) to formulate expectations on how the agency foresees institutions applying the updated *Guide*, devoting specific consideration to potential differences between the eighth and ninth editions. A similar approach was used in 2011 when NIH OLAW released [ten position statements](#) for public feedback, which later informed

[clarifications and updated language](#) from NIH to improve understanding and facilitate implementation. One key area that requires specific guidance is the use of the *Guide* at small and/or limited-resource institutions. These facilities experience unique challenges in complying with the *Guide* because of staffing shortages, infrastructure barriers, and difficult housing arrangements due to small numbers of animals, among other issues.

Advance copies of the *Guide* and a proposed implementation plan—coupled with opportunities to provide feedback—enable institutions to prepare for forthcoming changes while maintaining transparency. However, when publishing this information, it is imperative the consensus committee provides adequate response times for the full range of stakeholders to participate. While we recognize the National Academies operates under distinct operational timeframes than federal agencies, FASEB maintains the position that a minimum of 60 days is necessary to properly engage with the stakeholders that will use and refer to this document for years to come.

The Standing Committee’s previous attempts to engage with the public have been inadequate. For example, on November 15, 2023, the committee issued a call for experts to serve on the *Workshop Committee on Future Topical Updates to the Guide*, an event held in April 2024. The deadline of November 29 provided the public only 14 days to offer suggestions, which is even less feasible when a federal holiday occurred in between. Given the significance of the *Guide* and the potential policy implications associated with future updates, FASEB strongly urges the consensus committee to adopt sufficient comment timeframes to ensure relevant stakeholders can share thoughtful comments while respecting their internal governance processes.

***Recommendation 4: Postpone Implementation of a Living Document Until a Complete Understanding of Its Effects are Studied***

While FASEB appreciates the Standing Committee’s efforts to explore novel formats for the next edition of the *Guide*, we are concerned that transitioning to a living document is an overly ambitious endeavor at this time. Before introducing a new structure like a living document, it is essential to thoroughly study how the outstanding unknowns will impact the research community. Topics that warrant further investigation include but are not limited to: how revisions will be continuously updated, when updates go into effect, the impact of changes on active studies, how literature and accessory documents will be evaluated and reviewed, expectations for implementation, and how continuous changes will be communicated to the animal research community. Given these uncertainties, we suggest prioritizing content revisions and successful implementation of the new *Guide* before modifying its format.

**Conclusion**

FASEB appreciates the opportunity to offer comments 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.

Sincerely,

A handwritten signature in black ink that reads "Beth A. Garvy". The signature is written in a cursive style with a large, looping 'G' at the end.

Beth Garvy, PhD  
FASEB President